Environmental Defense Fund Comments on

Ten Scopes under the Toxic Substances Control Act

Docket IDs: EPA-HQ-OPPT-2016-0725 (Pigment Violet 29), EPA-HQ-OPPT-2016-0723 (1-4, Dioxane), EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene), EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride), EPA-HQ-OPPT-2016-0735 (HBCD), EPA-HQ-OPPT-2016-0736 (Asbestos), EPA-HQ-OPPT-2016-0737 (Trichloroethylene), EPA-HQ-OPPT-2016-0741 (1-Bromopropane), EPA-HQ-OPPT-2016-0742 (Methylene Chloride), and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone)

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The Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the scopes for the risk evaluations for the first ten chemicals being evaluated under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

In addition to specific comments on each chemical, EDF is providing broad comments addressing the scopes of risk evaluations for the first 10 chemicals as well as others in the future. While our comments are broadly applicable to all of the scope documents, we include examples from specific scopes to illustrate flaws and limitations.

As explained below, these scopes deviate from certain requirements of the law and in places are too unclear and vague or ambiguous to allow us to provide definitive comments. EDF recognizes that EPA was working under tight deadlines in producing these scopes – a problem it further exacerbated by EPA's decision to make major, late changes to the risk evaluation rule. EPA should take advantage of the upcoming problem formulation stage to address the many problems we identify below, and to more clearly and transparently explain its plans for these risk evaluations.

Before discussing the merits of the scoping documents, EDF provides the following clarification about its citation approach. Each scoping document contains largely identical, boilerplate language providing the agency's overall legal approach to "conditions of use" as well as its approaches on some other issues. Indeed, each document includes the same typos or misquotes of the underlying law. For ease of reference and to reduce excessive citations, EDF quotes from the asbestos scoping document and provides simply the page number when addressing these broader legal problems that are present in each scoping document. These comments equally apply to all scoping documents since they all contain

this same language; the only difference is page number. When EDF is specifically quoting another scoping document, we provide a citation clarifying that point.

Contents:

I. TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use.

EPA's scoping documents (pp.11-13) state that EPA has determined that "certain activities may not generally be considered to be conditions of use" (p.11) and also that EPA may "exclude certain activities that EPA has determined to be conditions of use" (p.12). EPA's approach asserts that EPA is allowed to ignore numerous circumstances falling within the statutory definition of "conditions of use" and is contrary to law. For the current set of chemicals under review, EPA may well be ignoring circumstances leading to ongoing exposures, and as a result, will fail to evaluate the risks the chemicals actually pose to human health and the environment.

TSCA's language and structure unambiguously foreclose EPA's interpretation. EPA's decision to disregard certain uses and exposures is also "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to consider "factors which Congress has not intended it to consider [and] entirely fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, as the scoping documents themselves reveal, this approach leads to irrational and arbitrary applications. Instead, EPA should be guided by the statutory language and consider all of those circumstances falling within the definition of "conditions of use." EPA should evaluate all of the circumstances revealed by the evidence of use and exposure, not ignore evidence because of self-imposed blinders.

A. The plain text, overall structure, purpose, and legislative history of TSCA indicate that EPA has to determine whether a chemical substance presents an unreasonable risk comprehensively, under all of its conditions of use.

i) *The plain text requires EPA to consider all conditions of use.*

Statutory interpretation should begin, as always, with the language of the statute. The plain language of both the risk evaluation provision and the definition of conditions of use support the interpretation that EPA must consider all circumstances falling within the statutory definition of "conditions of use." The main risk evaluation provision, TSCA § 6(b)(4)(A), directs that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). Inserting the statutory definition of conditions of use, this provision provides that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* §§ 2605(b)(4)(A), 2602(4). Thus, EPA has to analyze the risks of a substance under the circumstances described in the definition of "conditions of use," and no qualifying language allows EPA to exclude circumstances within that definition. The clause "as determined by the Administrator" calls for a factual finding or determination to be made by EPA. The relevant dictionary definition of "determine" is to "ascertain or establish exactly, typically as a result of research or calculation." OXFORD

AMERICAN DICTIONARY 474 (3d ed. 2010). While EPA may exercise reasonable judgment when interpreting "reasonably foreseen," nothing in this language grants EPA discretion to *ignore* factual circumstances that fall within the definition of "conditions of use." Indeed, statutes often direct agencies "to determine" things or make "determinations," and it is understood that the agency must make the finding required by the statutory language.

EPA's position that it can ignore known and foreseeable uses violates the text of the law. In the scoping documents, EPA asserts that it may ignore "legacy uses" and "associated disposals," impurities, alleged "de minimis" exposures, intermediates, conditions of use within closed systems, and conditions of use that have been analyzed by another regulatory agency (p.12). But "conditions of use" expressly includes "the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen to be to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). And every one of those circumstances is a "known" or "reasonably foreseen" "manufacture", "process[ing]," "use," or "disposal of" a chemical substance. Congress expressly chose to define "conditions of use" broadly to include not only "intended," but also "known" or "reasonably foreseen" manufacture, processing, distribution, use, and disposal. 15 U.S.C. § 2602(4). Disregarding chemical substances present as impurities or byproducts in the scoping documents, for example, because they are not "intended" essentially reads the other two scenarios out of the statute. Similarly, all the other identified conditions of use are also "intended, known, or reasonably foreseen." For example, EPA's scope suggests that 90% of the domestic production of Pigment Violet 29 "is processed as a site-limited intermediate." Pigment Violet 29, Scope at p.19, Docket ID: EPA-HQ-OPPT-2016-0725. It would absurd to ignore these intermediate uses when analyzing this chemical; doing so will lead to a truncated and incomplete analysis. Similarly the decision to exclude 1,4-dioxane's presence in numerous consumer, commercial, and industrial products as a byproduct of ethoxylation is entirely inappropriate, and will result in deficient and erroneous evaluation and determination of the chemical substance's risks. The same points can be made for many of the other chemicals used as intermediates or present as byproducts of chemical or product manufacture.

In contrast to the correct interpretation, EPA's new interpretation finds no support in the text. In the final risk evaluation rule (82 Fed. Reg. 33,726, 33,729 (July 20, 2017)), the only statutory textual basis for EPA's theory appears to be the "expects to consider" clause in the scope provision, TSCA § 6(b)(4)(D), requiring EPA to "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator *expects to consider*." 15 U.S.C. § 2605(b)(4)(D). But "expects to consider" does not mean "chooses to consider" or "prefers to consider." It is not the language of discretion; it is temporal language of anticipation or prediction. The dictionary definition of "to expect" is to "regard (something) as likely to happen." OXFORD AMERICAN DICTIONARY 609 (3d ed. 2010). This language indicates that, in the scope, EPA should describe what it anticipates studying, but it does not state that EPA has discretion to choose to ignore intended, known, or reasonably foreseen uses, hazards, or exposures. Moreover, the provision dictating what EPA must consider during a risk evaluation does not limit EPA's analysis to conditions of use identified in the scope. 15 U.S.C. § 2605(b)(4)(F). Indeed, EPA must consider all such conditions to fulfill its requirement that EPA account for the "likely duration, intensity, frequency, and

number of exposures under the conditions, where relevant." 15 U.S.C. 2605(b)(4)(F)(iv). Thus, the statutory language does not support EPA's assertion of discretion, including EPA's decision to limit its analyses to those factors identified in each scope. For example, under the rule of the last antecedent, the phrase "the Administrator expects to consider" does not even *modify* "conditions of use" or "hazards" or "exposures." Notably, EPA has so little regard for the statutory language that it repeatedly misquotes this language in significant ways.

Textually, EPA's argument also directly conflicts with TSCA § 26(k). 15 U.S.C. § 2625(k). TSCA § 26(k) requires EPA to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." *Id.* Notably, this requirement does not include *any* conditional phrase that modifies "conditions of use." And Congress included this provision to ensure that EPA could not ignore "reasonably available" "information relating to a chemical substance or mixture"; the purpose of this provision is to compel EPA to consider all reasonably available information. It would undermine this directive if EPA chooses to arbitrarily ignore certain uses and related exposures.

ii) *TSCA's overall structure requires EPA to consider all of the conditions of use.*

TSCA provisions direct EPA to prepare risk evaluations and the related findings for "chemical substances," *as a whole*, not for specific or limited conditions of use of those substances. For example, the risk management provision expressly requires EPA to address risks when the risks arise from combined exposure. TSCA § 6(a) provides that: "If [EPA] determines in accordance with [the risk evaluation provision] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, *or that any combination of such activities*, presents an unreasonable risk of injury to health or the environment," then EPA must issue a risk management rule. 15 U.S.C. § 2605(a); *see also* 15 U.S.C. § 2608(a) (using same language in provision governing requests to other federal agencies to address risks). Thus, if "any combination" of conditions of use presents an unreasonable risk, EPA must issue a risk management rule. But EPA must analyze *all* of these activities to assess whether *any combination* presents a risk.

When describing the end of a risk evaluation, TSCA requires EPA to make a finding about the "chemical substance" with no reference to conditions of use. *See, e.g.*, 15 U.S.C. § 2605(c)(1), (*i*) ("If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A)," then EPA must issue a regulation to address the unreasonable risk.). The absence of any reference to conditions of use makes it clear that EPA must make a finding for a chemical substance as a whole, not one limited to certain conditions of use. Notably, in the final prioritization rule, EPA correctly reasoned that this type of language indicated that EPA had to consider *all* uses in prioritization. *See* 82 Fed. Reg. 33,753, 33,755 (July 20, 2017) ("The statute directs EPA to make prioritization determinations on a 'chemical substance' or 'substance,' not on 'uses,' *see, e.g.*, 15 U.S.C. §§ 2605(b)(1)(A)-(C), and in most cases, without reference to 'the conditions of use.'"). This reasoning equally applies to risk evaluations.

iii) *TSCA's purpose, as well as basic logical reasoning and the best available science, require EPA to consider all conditions of use to assess a chemical substance as a whole.*

The purpose of the risk evaluation is to analyze the risks of a substance based on an assessment of its hazards and exposures. Ignoring potential exposures at the outset undermines that purpose. And science and logic do not support EPA's exceptions. For example, EPA states that it may disregard so-called "de minimis" exposures from conditions of use that occur in a closed system or use as an intermediate (p.12). But intermediates are often not completely consumed in chemical reactions and may remain as a residual in final reaction products. *See, e.g.*, California Department of Toxic Substances Control, Spray Polyurethane Foam Systems Containing Unreacted Methylene Diphenyl Diisocyanates, http://www.dtsc.ca.gov/SCP/Spray_Polyurethane_Foam.cfm (last visited Sept. 18, 2017). So the presumption that intermediates lead to a "de minimis" exposure is often contrary to the scientific evidence. In addition, intermediates must still be manufactured as well as typically being stored, transferred, or distributed, all of which are activities that can lead to exposures – including to workers, whom TSCA expressly identifies as a "potential exposed or susceptible subpopulation." Similarly, unintended impurities or contaminants can nonetheless lead to exposures and hence risks to human health or the environment, the significance of which needs to be determined in conducting a risk evaluation. *See infra* at pp.10-11 (discussing 1,4-dioxane). Ignoring them at the outset is contrary to the purpose of TSCA and risk evaluations, as well as the law's requirement that EPA rely on the best available science.

To be sure, EDF generally agrees with EPA's statement that "all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk." 82 Fed. Reg. at 33,734. Legally, EPA may be able to provide a concise and scientifically valid finding that a particular condition of use—such as the use phase of a chemical used as an intermediate—leads to little or no exposure and risk in a particular case, based on less than an in-depth analysis. And TSCA does not require a quantitative evaluation when a qualitative evaluation is determined and documented to be appropriate. But TSCA does not authorize EPA to simply "exclude" conditions of use at the outset as a matter of legal discretion. Furthermore, EPA must provide a scientific, data-backed rationale for why it decides a less extensive evaluation is sufficient, and cannot merely rely on a lack of data for such a decision.

EPA is imposing blinders on its analysis by asserting its authority to refuse to look at certain conditions of use, including known uses and disposals, and the result is that EPA is overlooking exposures in the real world. This approach is both contrary to law and arbitrary and capricious, as explained *infra* at Part I.D.

iv) *The legislative history does not justify or even lend support to EPA's approach.*

To justify its new position, EPA has emphasized the "legislative history" (p.11). But the legislative history, read as a whole, does not support EPA's approach. In the risk evaluation rule, EPA claims that the "legislative history of the amended TSCA *** explicitly states that the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation." 40 Fed. Reg. at 33,728 (citing 114 Cong. Rec. S3519-20 (daily ed. June 7, 2016) (statement of Sen. Vitter)). EPA relies on a floor

statement from a single Senator, which is one of the least illuminating forms of legislative history. EPA ignores that the rest of the legislative history reveals that other Senators thought that the statutory language would require EPA to consider all conditions of use in risk evaluations under the Lautenberg Act. Four principal Democratic negotiators of the legislation submitted a statement to the record that: "[t]he definition of 'conditions of use' described above plainly covers all uses of a chemical substance." 114 Cong. Rec. S3516 (daily ed. June 7, 2016). Similarly, when explaining why the bill expressly "grandfathered" in prior risk assessments (such as for Methylene Chloride), these negotiators explained that the provision was necessary because those "risk assessments for these chemicals were not conducted across all conditions of use." *Id.* at S3519. This explanation clearly reflects that *future* risk evaluations under TSCA would have to be conducted "across all conditions of use."

Unlike the text and structure of TSCA, the legislative history is somewhat ambiguous at points, although, if anything, it supports the position that EPA must consider "all conditions of use" since more Senators expressed that view and they did so in a formal statement.

B. Conditions of use expressly include certain so-called legacy uses and associated disposals.

In each of the scopes EPA stated that it *will* exclude so-called "legacy uses" and "associated disposal," (p.12) and EPA appears to rely on its reasoning from the risk evaluation rule. 82 Fed. Reg. at 33,729-30. EPA has asserted that no statutory text addresses this issue, and EPA stated that the use of the phrase "to be" in the definition of "conditions of use" implies a prospective application. 82 Fed. Reg. at 33,730; *see* 15 U.S.C. § 2602(4) (defining conditions of use to "mean[] the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen *to be* manufactured, processed, distributed in commerce, used, or disposed of") (emphasis added). EPA also (inaccurately) asserted that it did "not have an effective tool to address risks found to arise from uses in consumer settings if there" is no on-going manufacture, processing, or distribution. 82 Fed. Reg. at 33,730. But none of this reasoning survives scrutiny.

EPA's argument based on tense clearly does not apply to the legacy uses and associated disposals. If a chemical substance is present in a product or material that an industrial, commercial, or residential consumer is still using, then the substance is known "to be" used in that circumstance. Similarly, if a substance has not been disposed of yet, its disposal is in the future and reasonably foreseeable. As a result, these "legacy uses" and "associated disposal[s]" fall squarely within TSCA's definition of "conditions of use," which includes the "circumstances *** under which a chemical substance is *** known *** to be *** used, or disposed of." 15 U.S.C. § 2602(4). EPA has presented no textual basis for treating the first three participles in the list in this definition (manufactured, processed, and distributed in commerce) differently than the last two participles (used and disposed of).

EPA's theory that § 6 focuses on the "continuing flow of chemical substances" in "their lifecycles" (p.12) completely ignores that the use and disposal of a chemical is *part* of the lifecycle of a chemical, as defined by Congress in TSCA. Indeed, chemicals that are still in use are still "distributed in commerce" as that term is defined in TSCA. 15 U.S.C. § 2602(5). In the final risk evaluation rule, EPA stated that it

"believes the statute is better interpreted to focus on the prospective flow of the chemical substance," 80 Fed. Reg. at 33,730, but Congress expressly covered substances *after* their introduction into commerce as well.

EPA also justified its decision to ignore legacy uses by claiming it lacks tools to address risks from uses in consumer settings if there is no on-going commercial manufacture, processing, or distribution. 80 Fed. Reg. at 33,730. But TSCA § 6(a) expressly provides EPA with authorities that could manage some of these risks, even if it does not provide as broad authority as it does over manufacturers and processors. *See* 15 U.S.C. § 2605(a). For example, at risk management, EPA may impose "[a] requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture." *Id.* § 2605(a)(5). For example, EPA could ban the sale or future use of products containing a chemical even if that chemical is no longer in production in the United States, or EPA could require that such items be labeled. EPA may also impose "[a] requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or *by any other person* who uses, or disposes of, it for commercial purposes." *Id.* § 2605(a)(6)(A) (emphasis added).

In any event, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Indeed, in order to assess real-world risks of a chemical using the best available science, EPA needs to consider even those exposures over which it has limited or shared control. This approach is particularly appropriate given TSCA § 9's referral provisions.

C. The text and overall structure of TSCA makes it clear that EPA has to analyze uses, even if they have been assessed by another agency or are within another agency's jurisdiction.

EPA also stated that it may "exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risk" (p.12). But EPA provides no textual basis for ignoring those uses, which are often "circumstances *** under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Nothing in the risk evaluation provision or definition of conditions of use authorizes EPA to ignore conditions of use because of other agencies' jurisdiction over chemical substances. And several other provisions of TSCA indicate that Congress intended for EPA to consider such exposures, except to the extent Congress explicitly provided otherwise.

First, TSCA § 9(a) provides a detailed procedural mechanism for EPA under certain circumstances to request for another federal agency to address an unreasonable risk arising from a chemical substance that EPA has identified. 15 U.S.C. § 2608(a). This request then triggers a number of duties for both EPA and the other agency, requiring one of the two agencies to take action to address the risk. Thus Congress intended for EPA to prepare risk evaluations analyzing uses that might be addressed by another agency, and Congress created a substantive and procedural mechanism to resolve overlapping jurisdiction only *after* completing the risk evaluation. If EPA could just ignore risks arising from

conditions of use that fall within other agencies' jurisdiction, or if Congress meant for EPA to defer to those agencies' current regulatory approach to those chemicals at the outset before conducting a risk evaluation, then EPA might never make the finding that triggers the § 9(a) process. Here again, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Given that Congress expressly addressed the issue of overlapping regulatory jurisdictions in TSCA § 9, EPA cannot avoid those procedures by simply ignoring uses that fall within another agency's jurisdiction. Furthermore, EPA is expressly required to evaluate exposures from combinations of activities, which it cannot do if it excludes conditions of use at the outset that have been evaluated or regulated by another agency, particularly when that risk management is not an outright ban.

Second, Congress expressly exempted certain regulated chemicals or uses of chemicals from EPA's authority when it defined "chemical substance" in TSCA § 3(2). 15 U.S.C. § 2602(2)(B). For example, "chemical substance" does not include certain materials as defined in the Atomic Energy Act of 1954. *See id.* § 2602(2)(B)(ii), (iv). Thus, when Congress intended for EPA not to regulate certain conditions of use because they were regulated under other specific federal statutes, Congress expressly excluded those conditions of use. That Congress chose a limited, specific set of exclusions indicates that Congress did not intend for EPA generally to ignore other conditions of use even where they fall under other federal regulatory schemes.

D. The scopes contain incoherent and arbitrary and capricious reasoning because of EPA's approach to conditions of use.

EPA's illegal approach to "conditions of use" leads it to put "blinders" on regarding certain uses, exposures, and risks. The result is "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to have considered "factors which Congress has not intended it to consider [and] entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. It also violates several provisions of TSCA § 26 because by ignoring uses, exposures, and related information, EPA will not be acting "consistent with the best available science," EPA will not base decisions on "on the weight of the scientific evidence," and EPA will not "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h), (*i*), (k). In addition, because EPA's distinction is a false one untethered to the information, EPA seems to treat certain conditions of use inconsistently throughout the documents.

For example, in the 1,4-dioxane scope, EPA states that it will not consider risks arising from 1,4-dioxane when it is present as a by-product or residual contaminant from the manufacture of other chemicals. *See* 1,4-Dioxane, Scope at p.21, Docket ID: EPA-HQ-OPPT-2016-0723. But EPA identifies numerous products that "potentially contain[] 1,4-dioxane as a residual contaminant, including paints, coatings, lacquers, ethylene glycol-based antifreeze coolants, spray polyurethane foam, household detergents, cosmetics/toiletries, textile dyes, pharmaceuticals, foods, agricultural and veterinary products," as well as "magnetic tape and adhesives." *Id.* These are known and reasonably foreseen conditions of use

leading to exposures to 1,4-dioxane, and EPA's decision to ignore them when analyzing whether this chemical presents an unreasonable risk is arbitrary and capricious. EPA's theory is that it cannot regulate these impurities until it analyzes ethoxylated chemicals (*id.* at 8), but EPA provides no reasoned legal theory for why it could not act to regulate these exposures after this risk evaluation. *Id.* Even more problematically, EPA staked out the position that "EPA may choose not to include a particular impurity within the scope of any risk evaluation." 82 Fed. Reg. at 33,730. So these exposures may never be analyzed.

In addition, EPA acknowledges that 1,4-dioxane is often used as an intermediate or a reactant and that "the 1,4-dioxane would react either fully *or to a lesser extent*. Following completion of the reaction, the produced substance *may or may not be purified further*, thus removing unreacted 1,4-dioxane (if any exists). Reacted 1,4-dioxane is *assumed* to be destroyed and is thus not expected to be released or cause potential worker exposures." *See* 1,4-Dioxane, Scope at p.56, Docket ID: EPA-HQ-OPPT-2016-0723 (emphases added). But EPA never acknowledges that the unreacted 1,4-dioxane could lead to exposure. And that document provides no explanation, documentation, or quantification supporting the underlying assumption that 1,4-dioxane is destroyed or reacted. Indeed, from the description, it seems clear that it often will not be destroyed. The assumption in the last quoted sentence is contrary to the statements made in the proceeding sentences.

EPA's scopes should indicate that it will assess the reasonably available information on hazards and exposures for the substances (see Section II below), and that information should inform EPA's evaluation of the risks associated with "the conditions of use." If there is a real-world exposure, then EPA should not ignore it.

II. EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA §§ 4 and 8 to obtain additional information.

TSCA orders EPA to consider "available" and "reasonably available" information in crafting a risk evaluation, 15 U.S.C. §§ 2605(b)(4)(F)(i), 2625(k), and under the new risk evaluation rule, EPA defined "[r]easonably available information" to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 C.F.R. § 702.33, promulgated at 82 Fed. Reg. 33,748 (July 20, 2017). Thus, under its own rule, EPA has to consider information that it "can reasonably generate, obtain, and synthesize."

Yet, the scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is *reasonably* available information.

A. Any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities.

EPA must promulgate reasonable regulations under § 8(d) and 8(a) to obtain information about hazards, exposures, and conditions of use for these ten chemicals; EPA should also exercise its authority under § 8(c) to obtain additional information. Consistent with TSCA § 8(a)(5), EPA can take steps to reduce unnecessary and duplicative reporting. Because TSCA requires EPA to produce robust risk evaluations that reflect "reasonably available" information, and information available under these authorities is "reasonably available" on its face, EPA must use these authorities to fulfill its duty. Moreover, these first ten risk evaluations are crucial to establishing the credibility of the TSCA program under the Lautenberg Act, and EPA can only establish that credibility by using its full authority to obtain "reasonably available information" on chemicals, as required by the law. Collecting this information is also necessary to fulfill EPA's duty to use the best available science under TSCA § 26.

TSCA § 8(d) allows EPA to "require any person who manufactures, processes, or distributes in commerce *** any chemical substance or mixture *** to submit to the Administrator—lists of health and safety studies: (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person; or (C) reasonably ascertainable by such person." 15 U.S.C. § 2607(d). EPA should issue § 8(d) rules for these ten chemicals. To obtain a complete picture, EPA should expressly require both manufacturers and processors to report on these chemicals under the § 8(d) rules. *See* 40 C.F.R. § 716.5(c).

EPA has previously issued such rules for some of these chemicals, but two decades have passed since the last of those rules sunsetted, so new, additional health and safety studies are almost certainly available. For example, the methylene chloride and asbestos reporting periods sunsetted in 1992, the HBCD reporting period sunsetted in 1995, and the perchloroethylene reporting period sunsetted in 1997. *See* 40 C.F.R. § 716.120. Given scientific advancement over the last two decades, issuing new rules calling in health and safety studies would likely provide EPA with additional valuable information to assess the hazards, exposures, and risks posed by these chemicals. It appears that EPA has never issued such rules for Carbon Tetrachloride, Trichloroethylene, Pigment Violet 29, 1-Bromopane, 1-4 Dioxane, and N-Methylpyrrolidone. *See* 40 C.F.R. § 716.120. Thus, issuing § 8(d) rules for those chemicals is even more important.

Notably, EPA's regulations correctly interpret "health and safety study" broadly to incorporate "[a]ny data that bear on the effects of a chemical substance on health or the environment." 40 C.F.R. § 716.3. These include numerous tests for health and environmental effects. *See id.* They also include monitoring data and other assessments of human and environmental exposures. *See id.* EPA should also review these studies upon receipt and request underlying data under 40 C.F.R. §§ 716.10(a)(4), 716.40(a). EPA should also separately request reporting on these chemicals when they are manufactured, processed, or distributed as an impurity, 40 C.F.R. § 716.20(a)(9), because impurities may be an important source of exposure and thus risk, as explained above.

Under TSCA § 8(a), EPA may require manufacturers and processors to provide extensive information. *See* 15 U.S.C. § 2607(a)(2). EPA "shall, to the extent feasible" "not require reporting which is unnecessary or duplicative" and also "apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title." *Id.* § 2607(a)(5). To avoid duplication, EPA need not request reporting on information EPA has already obtained through other recent submissions such as through the Chemical Data Reporting (CDR) process. *See* 40 C.F.R. Part 711. But the CDR process does not require manufacturers and processors to provide all information that EPA can reasonably obtain under TSCA § 8(a) which is relevant to the risk evaluations. For example, EPA should require reporting of: "[a]ll existing information concerning the environmental and health effects of" each chemical; "the byproducts resulting from the manufacture, processing, use, or disposal of each" chemical; more detailed information about exposures to these chemicals, including the duration, frequency, and timing of exposures; and additional information about disposal. *See* 15 U.S.C. § 2607(a)(2). In particular, EPA can require submission of any data available on releases or exposures in the workplace and environment, and those data would be crucially important to an accurate risk evaluation. To decrease the burden on industry, EPA should pursue both rulemakings simultaneously, and EPA can provide that when information is submitted under one rule, the same information need not be submitted under the other. But EPA should use both authorities to ensure that it does not miss any information that may fall within one authority but not the other.

In addition, EPA should rely on its request authority under TSCA § 8(c). Under TSCA § 8(c), "[a]ny person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture." 15 U.S.C. § 2607(c). EPA promulgated rules governing this recordkeeping requirement at 40 C.F.R. Part 717. The rules apply to most manufacturers and many processors. 40 C.F.R. § 717.5. Manufacturers and processors must maintain records of many types of allegations, as detailed in 40 C.F.R. §§ 717.5 and 717.10. The regulation defines "significant adverse reactions" to include, but not be limited to, many specific types of harm that are highly relevant to the ultimate question presented in a risk evaluation: "whether a chemical substance presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(b)(4)(A). Firms must maintain these records for 30 or 5 years, depending on the circumstances. 40 C.F.R. § 717.15(d).

EPA should use its authority to request these records on alleged significant adverse reactions caused by the ten chemicals analyzed in the scope documents and add them to the administrative record for the relevant chemical. EPA can request records from manufacturers and processors that reported the chemicals in response to any § 8(a) and 8(d) rules or in response to CDR reporting. *Id.* § 717.17. EPA can request those records by letter. *Id.* § 717.17(b). Finally, EPA can also notify all people holding such records to provide them by a notice in the Federal Register. *Id.* These records may provide valuable information on hazards, exposures, and conditions of use, since the records may reveal not only significant adverse reactions but also information about the specific exposure and use that may have caused the reaction.

B. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps.

EPA should make robust use of its § 4 authority to fill any gaps in information. EDF recognizes that time constraints apply to these first ten chemicals and thus some types of testing may not be possible, but going forward, EPA needs to use its authority fully and do so in a timeframe that ensures it will have all of the information it needs to conduct risk evaluations.

As EPA moves forward on the first 10 risk evaluations, it should first clearly identify *all* significant information gaps on hazards or exposures. Based on its own regulation, EPA must then use its authority under TSCA § 4(a)(2) to require the development of new information to fill those gaps wherever possible. Information that EPA can generate under TSCA § 4(a)(2) is reasonably available under EPA's own regulation as "information that EPA *** can reasonably generate [and] obtain *** for use in risk evaluations." 40 C.F.R. § 702.33. Thus, EPA should identify such information gaps and then promptly require the conduct of all testing that can be done and still meet the statutory deadlines for the risk evaluations.

TSCA § 4(a)(2) provides that EPA "may, by rule, order, or consent agreement require the development of new information relating to a chemical substance *** if the Administrator determines that the information is necessary *** to perform a risk evaluation under section 6(b)." 15 U.S.C. § 2603(a)(2)(A)(i). Congress provided this additional testing authority allowing EPA to require testing or other data development efforts solely upon a determination "that the information is necessary *** to perform a risk evaluation under section 6(b)." *Id.* In light of deadlines, EPA can and should use its order authority and does not need to make the additional findings required for a rule under TSCA § 4(a)(1).

In places in these scopes, EPA seems to be going out of its way to avoid using its information authorities. For example, in numerous places in these scopes, with respect to exposure, EPA indicates that "[f]or conditions of use where data are limited or not available, [it will] review existing exposure models that may be applicable in estimating exposure levels" (p.43). This language suggests that EPA will simply default to models rather than use its authority to get needed information. In EDF's view, EPA should first use its authorities under TSCA §§ 8 and 4 to fill those information gaps, rather than rely on models to compensate for lack of information. This is not to say that exposure models do not have a role, but they are not a basis for avoiding the obligation to collect information.

Our review of the scopes indicates that there are significant gaps in the information. Where possible EPA needs to fill those gaps. When it is not possible, consistent with TSCA § 26, EPA needs to identify those gaps and characterize the uncertainty in the draft risk evaluations. To cite just one example, in the scope for Methylene Chloride EPA completely fails to mention an information gap earlier identified in the Work Plan. Specifically, the 2014 Work Plan Assessment for Methylene Chloride identified both developmental neurotoxicity and immunotoxicity from chronic exposure as important data gaps, impacting the selection of the point of departure:

> There is uncertainty about chronic exposure impacts on the nervous system function. The nervous system has been well studied and identified as very sensitive for acute effects. However, there is a paucity of data on chronic neurological impacts, especially developmental neurotoxicity. Likewise, there is limited information about immunotoxicity following chronic exposure to DCM. Existing hazard studies are not sufficient for dose response analysis to provide a lower point of departure than existing adverse findings in the liver from chronic exposures."

See Methylene Chloride: Paint Stripping Use, TSCA Work Plan Chemical Risk Assessment at p.115, https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf

C. If EPA already has relevant information, it is reasonably available and EPA should consider it.

The strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." *See, e.g.*, Asbestos literature at p.13. But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation *** is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available, EPA must review it.

In addition, much of this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. First, historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act. Second, the Lautenberg Act greatly increased the requirements companies must meet to assert CBI claims. For example, information only qualifies for protection if the submitter asserts *and* substantiates that it has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c). Thus, even if the information once merited protection, it may no longer be confidential under the standards of TSCA § 14. Third, as a general rule, TSCA § 14(b)(2) provides that health and safety studies and information from health and safety studies are not entitled to confidential treatment, so much of this information may not be confidential under that provision.

To fulfill its duties under TSCA, EPA must review this reasonably available information and identify that which is potentially relevant to the risk evaluations. Where information is relevant, EPA should also consider whether the information meets the strict requirements for nondisclosure under TSCA § 14. If not, EPA should add it to the administrative record for review by the public. Whether or not it meets those requirements, EPA should then determine whether and how to consider the information in evaluating these chemicals. Notably, TSCA § 26(j) requires that, "subject to section 14," EPA "shall make

available to the public *** a list of the studies considered by [EPA] in carrying out each such risk evaluation, along with the results of those studies." 15 U.S.C. § 2625(j).

D. When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information.

In the literature searches, EPA sometimes states that it relied on recent assessments, and then only performed research for dates beyond those assessments. *See, e.g.*, 1,4-Dioxane, Strategy for Conducting Literature Searches for 1,4-Dioxane: Supp. File for the TSCA Scope at p.7, 9-10, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0047. EPA needs to provide a short analysis presenting its review of the prior analysis to ensure it adequately captured and addressed all reasonably available information as of the date of its publication, particularly given the expanded obligations under the Lautenberg Act. If EPA finds it was not adequate, then EPA should broaden its literature search.

III. EPA needs to take additional steps to ensure both the completeness and accuracy of the information it relies upon.

As explained above, EPA should rely on its authorities under TSCA §§ 8 and 4 to obtain all reasonably available information. Those authorities include a number of measures to ensure the accuracy and completeness of the data relied upon. To the extent EPA relies on voluntarily submitted information, EPA needs to take additional steps to ensure the accuracy and completeness of the information. Otherwise, EPA will violate TSCA § 26 by failing to make decisions "in a manner consistent with the best available science." 15 U.S.C. § 2625(h)

A. EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals.

EPA has requested in each of the scopes that industry and other stakeholders provide information. While this voluntary request was a reasonable first step towards obtaining the necessary information, EPA has failed to provide any account for how this voluntary approach to collecting information will result in EPA obtaining all "reasonably available" information as EPA has defined that term. There are several obvious problems and limitations with this voluntary approach which EPA has not even acknowledged, much less addressed.

First, a voluntary call is much less likely to produce all of the necessary information than rules mandating that affected parties provide the requested information. If manufacturers and processors are legally required to provide the information, that legal obligation provides a strong incentive for them to collect and submit all relevant information. Absent that incentive, some companies may choose to focus time and attention on other matters. Indeed, the burdens (whether one considers them heavy or light) of collecting and submitting information counsel in favor of issuing mandatory rules. *If* the process of

collecting and submitting the information is not onerous or difficult, then using rules to require the submission of the information will do little if any harm to the regulated industry, and use of rules will ensure EPA has a complete picture and increase credibility. Alternatively, to the extent that the process is onerous or difficult, it is even more important that EPA *require* the submission of the information, because otherwise those burdens will likely discourage stakeholders with relevant information from collecting and submitting the information.

Second, EPA has provided no empirical evidence establishing that this voluntary approach will result in EPA obtaining all "reasonably available" information. Unless EPA has some empirical basis for stating that the voluntary approach will allow EPA to obtain all reasonably available information that it can obtain under its legal authorities, EPA must rely on its existing authorities to obtain a complete set of information.

Indeed, EPA's prior experience with voluntary reporting provides strong evidence that a voluntary approach is unlikely to provide complete and accurate data. For example, an EPA advisory committee called for the development of nanomaterial reporting rules in 2005, but EPA instead spent several years developing and carrying out a voluntary reporting program, the Nanoscale Materials Stewardship Program (NMSP). This voluntary reporting program produced minimal information as revealed by EPA's 2009 interim report on the NMSP. Nanoscale Materials Stewardship Program, Interim Report, OPPT (Jan. 2009), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0003. "[I]n the report EPA estimated that companies provided information on only about 10 percent of the chemical substances manufactured at the nanoscale that may be commercially available in 2009." 80 Fed. Reg. 18,330, 18,334 (April 6, 2015). In 2017, over a decade after the data need was identified, EPA finally finalized a § 8(a) reporting rule to acquire the data. 82 Fed. Reg. 3641 (Jan. 12, 2017). Given the past failures of voluntary approaches, EPA should not rely on them here.

Third, manufacturers and processors of these chemicals have a vested interest in EPA finding that the chemicals do not present an unreasonable risk. A no-unreasonable-risk finding reduces the likelihood of government regulation, including potential restrictions on risky chemicals, and it may reduce any stigma they may otherwise face in the marketplace. The financial costs of regulation may ultimately be very high for some specific firms and individuals, and even if not, many firms and individuals may *believe* that the costs of regulation will be high. These companies have a "financial interest" in the outcome of these proceedings, and they are not impartial. *See, e.g.*, 28 U.S.C. § 455(b)(4) (requiring Judges to disqualify themselves in proceedings where they have a financial interest). Because of this reality and appearance of partiality, relying solely on voluntary measures decreases the credibility of these risk evaluations.

Relying solely on voluntary presentation of information raises the concern that the companies or trade associations may present an incomplete or skewed picture. Companies and trade associations may choose to "cherry pick" information and provide only the information that paints their chemicals in favorable light. They may provide only summaries of information that reflect conscious and subconscious judgment calls that result in unduly favorable conclusions; and without access to the full information neither EPA nor the public can independently assess such conclusions. They may choose

not to review records robustly when the review may disclose unfavorable information. They may seek to put their best foot forward and describe the ideal scenario of use and safety measures. Or, if they have unfavorable information, they may choose not to provide any information at all and simply not participate in these proceedings.

To be sure, members of the regulated community are crucial sources of information about their chemicals' uses, hazards, and exposures, but EPA cannot simply assume that they will voluntarily disclose unfavorable or complete information about their practices and products. *See* THE FEDERALIST NO. 51 (James Madison) ("If men were angels, no government would be necessary. *** [E]xperience has taught mankind the necessity of auxiliary precautions."); *Williams v. Pennsylvania*, 136 S. Ct. 1899, 1905-06 (2016) ("Bias is easy to attribute to others and difficult to discern in oneself. *** This objective risk of bias is reflected in the due process maxim that 'no man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome.'"). Here, manufacturers and processors obviously have an interest in the outcome, and EPA must craft its procedures and approaches with that reality in mind. Requiring the submission of information is the safest approach to ensuring that these parties provide all relevant information, and that is in turn crucial to establishing and demonstrating the credibility of this process.

If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information. First, EPA can require that certain information and underlying information be provided in full, which ensures completeness. In addition, a § 8(d) rule requires that people engage in an adequate search of records. 40 C.F.R. § 716.25. Second, submitters must file certification statements by authorized officials that certify that the submitted information has been submitted in compliance with the requirements of this process. *See, e.g.*, 40 C.F.R. § 711.15(b)(1). Third, submitters often must retain records of required submissions for a period of five years, and the retention of records can help encourage accurate reporting since those records would be available should a submission latter be investigated. *See, e.g.*, 40 C.F.R. § 711.25. None of these features apply to the voluntary requests for information EPA has indicated it is relying on.

In addition, as EDF has explained in prior comments, there are numerous reasons that it is important that the public have access to full studies and the underlying information, not simply robust or other study summaries. *See, e.g.*, EDF Comments on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act, Comment at p.37, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074. Without access to full studies, the public will be challenged or unable to assess and comment on the quality of the studies used by the agency. *Id.* EDF reincorporates and reiterates the numerous points made in support of public access to the full studies here. *Id.* These points also support the importance of EPA obtaining the full studies.

B. For voluntary submissions, EPA should take additional steps to ensure completeness and accuracy and to vet information based on underlying data.

To the extent it relies on voluntary submissions, EPA can and should take additional steps to better ensure that the voluntary information it receives is accurate and complete. EPA would need to develop a far more rigorous and structured process than it currently has. For example, EPA's submission process does not appear to require anyone to certify that the information in their comments is accurate or complete to the best of their knowledge. EPA should consider approaches for vetting statements and assertions, particularly when made by entities with a financial interest in the outcome of these risk evaluations.

EPA should also request that submitters always provide full studies, as well as underlying data whenever reasonably available or obtainable. Setting aside concerns about partiality, EPA needs the underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular submission.

In addition, EPA should seek input directly from workers for manufacturers and processors, providing them an easy method to submit information on workplace practices and conditions independently from management. EPA needs to take steps to allow workers to provide input in a manner that reduces the risks of any potential retaliation from management.

To give a few specific examples from the scopes:

In the Perchloroethylene scope (also known as tetrachloroethylene or PCE), EPA cites the Vinyl Institute's comments for the fact it can be a residual or byproduct in the manufacture of other chemicals. *See* Perchloroethylene, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0732 (citing comment at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0013). That comment, in turn, contains a table claiming to summarize the approximate concentrations of Perchloroethylene in light and heavy end liquid intermediate streams yielded in the EDC/VCM process for manufacturing each of four chlorinated organic substances. The comment states that there is no residual Perchloroethylene in light liquid ends and 1.1% by typical weight in heavy liquid ends. But the comment does not provide or cite any underlying data supporting these findings. When commenters provide summary statements along these lines, EPA should give them little weight unless it also receives the underlying data to ensure that the reported results or conclusions drawn accurately reflect real-world conditions and to assess the level of certainty and scope of applicability that EPA can attribute to the results or conclusions. This point holds for all of the percentages set forth in that table, including those for the other three products.

Similar concerns arise for many of the other scopes. For example, in the Carbon Tetrachloride scope, EPA states that: "there are public comments, EPA-HQ-OPPT-2016-0733-0005 [3M] and EPA-HQ-OPPT-2016-0733-0017 [ACC], stating that carbon tetrachloride may be present in a limited number of industrial products with chlorinated ingredients at a concentration of less than 0.003% by weight." Carbon Tetrachloride, Scope at p.20, Docket ID: EPA-HQ-OPPT-2016-0733. But upon examining those

comments, they do not provide any of the underlying data or enough information to assess accuracy of the statement or the level of uncertainty that should apply to the results. The ACC comment is particularly difficult to assess. It involves multiple levels of hearsay, with ACC reporting statements that companies reported to it. Some of those companies acknowledge they are also relying on hearsay from suppliers and have not taken steps to confirm these concentrations. Those suppliers might also be relying on hearsay; it is simply not clear what the bases are for some of these values. Hearsay is, of course, particularly problematic when the statement serves the interest of the person submitting the evidence. *See, e.g.*, FED. R. EVID. P. 804(b)(5) (exception for statements against interest). As such, these concentrations arguably provide at best a "lower bound" estimate; they are not sufficient in terms of establishing that the actual concentrations are not higher. While no formal hearsay rule applies to these administrative proceedings and the hearsay evidentiary rule generally has limited applicability to technical studies and business records, it is relevant to the weight EPA should give these reported values given these circumstances. ACC does not disclose the companies providing the information, making it impossible for EPA to independently address these kinds of concerns. In addition, ACC's comment often fails to provide any clarity or detail as to how the concentrations were measured or assessed, much less provide the data underlying these claimed concentrations. The ACC comment asserts concentrations for 1,4-Dioxane, Pigment Violet 29, N-Methylpyrrolidone (NMP), Methylene Chloride (DCM), Carbon Tetrachloride, and HBCD, but for most of these concentrations, it is impossible for EPA or the public to assess whether they are accurate. For some of these concentrations, the comment states that Safety Data Sheets and Technical Data Sheets are provided with the comments, but EDF did not find any attachments with the comment containing those materials. In sum, EPA needs to scrutinize these voluntary submissions carefully and ensure access to the underlying information, which is necessary to assess the accuracy of the statements therein.

In the asbestos scoping document, EPA acknowledged that the analysis of the Chlor-Alkali industry was "primarily based on information provided by either the chlor-alkali industry or [the American Chemistry Council] and is meant to represent typical practices." *See* Asbestos, Scope at p.54, Docket ID: EPA-HQ-OPPT-2016-0736. EPA correctly recognized that EPA should "further evaluate how representative the processes witnessed at these two facilities are of processes at other plants." *Id.* at 23. EPA should take measures to ensure that its process will in fact accurately assess the full range of existing practices, relying on independent data where possible. Where independent data are unavailable, EPA should reach out to workers directly to better determine actual practices. Even when companies have good practices on paper, those practices may not be the reality on the ground.

EPA also needs to carefully scrutinize statements to ensure it correctly interprets them.

IV. These scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations.

Broadly viewed, the scopes do not meet several of the statutory requirements of TSCA. TSCA § 6(b)(4)(D) requires that EPA "shall, not later than 6 months after the initiation of a risk evaluation,

publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D). These scopes do not fully satisfy these requirements. Some aspects are plainly illegal under *any* interpretation of the statute, for the reasons given above, such as the statement that "EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11).[1] But many other aspects, while problematic, can be resolved by EPA in the next step: its development of problem formulations.

It is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. EDF believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified. With respect to susceptible populations, EPA should consider workers and, in most cases, pregnant women and children, to be potentially exposed or susceptible subpopulations. We identify below a number of specific examples where EPA's scopes are unclear and merit further study.

A. 1,4-Dioxane

EPA states: "EPA evaluated the weight of the evidence for cancer in humans and animals and concluded that 1,4-dioxane is 'likely to be carcinogenic to humans' based on evidence of carcinogenicity in several 2-year bioassays." 1,4-Dioxane, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0723. However, certain language in this section suggests that EPA may not include cancer as a hazard endpoint in the risk evaluation.

Indeed, EPA almost seems to suggest that inconclusive evidence regarding the "mode of action by which 1,4-dioxane produces liver, nasal, peritoneal (mesotheliomas) and mammary gland tumors" might form a basis for disregarding the evidence of such hazards. *Id.* at 35. As a general matter, EPA should not exclude observed hazards simply because the underlying MOA is not fully delineated or understood, doing so would significantly and inappropriately jeopardize the robustness and health-protections of the risk evaluation. If there is evidence of hazard, EPA should include it in the risk evaluation, even if the precise mode of action is not yet understood.

[1] As explained above, EPA puts too much weight on a floor statement from a single Senator, David Vitter. But even Senator Vitter stated that EPA must consider all conditions of use identified in the scope. *See* 114 Cong. Rec. S3520 (daily ed. June 7, 2016) (statement of Sen. Vitter). Despite that statement, the scoping documents all state that "during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11). Thus, EPA is inconsistent in how much weight it gives to Senator Vitter's statements, and EPA's current interpretation appears to contradict the views expressed throughout the legislative history by every single legislator. If EPA excluded uses identified in the scope, such as uses in the chlor-alkali industry (e.g., pp.20, 23-24), then EPA will be acting contrary to Senator Vitter's statement.

B. Perchloroethylene

The scope for Perchloroethylene states that "EPA expects to consider hazards identified in the recent assessment by the EPA Integrated Risk Information System (IRIS) Program: neurotoxicity, kidney toxicity, liver toxicity, developmental and reproductive toxicity and cancer. Support for an association with immune and blood effects was less well characterized." Perchloroethylene, Scope at p.11, Docket ID: EPA-HQ-OPPT-2016-0732. It is unclear from the scope whether EPA intends to include immune and blood effects in particular.

C. Trichloroethylene (TCE)

In the scope for TCE, EPA suggests that TCE's use as a spot remover will not be analyzed because it was previously analyzed in a risk evaluation. TCE, Scope at p.25, Docket ID: EPA-HQ-OPPT-2016-0737. That approach may be reasonable if EPA finalizes its proposed ban on this use of TCE to address those risks, as discussed more below. But that approach only applies to those spot remover uses that have previously been analyzed, specifically commercial dry cleaning facilities. This risk evaluation needs to consider TCE's use as a consumer spot remover. Those uses have not been analyzed in-depth, and the 2014 work plan assessment recognized that some such products may contain TCE as a main ingredient. *See* Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses, TSCA Work Plan Chemical Risk Assessment at p.52, https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

D. N-Methylpyrrolidone (NMP)

The NMP scope has numerous inconsistencies with respect to its identification of the endpoints to be assessed. EPA begins by acknowledging that a "number of human health hazards have been identified for NMP including adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems." N-Methylpyrrolidone, Scope at p.36, Docket ID: EPA-HQ-OPPT-2016-0743. EPA also states that: "EPA expects to consider all potential hazards associated with NMP." *Id.* EDF completely agrees with that approach. However, the description under section 2.42 Human Health Hazards indicates that EPA intends to focus on a narrower set of hazards (acute toxicity and reproductive/developmental toxicity), and provides no justification or even explanation for excluding some of the hazards that it previously identified.

E. Potentially exposed or susceptible subpopulations

EPA also does not identify pregnant women, women of childbearing age, or the developing fetus as potential exposed or susceptible subpopulations for either N-Methylpyrrolidone (NMP) [NMP, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0743] or TCE [TCE, Scope at pp.37-38, Docket ID: EPA-HQ-OPPT-2016-0737], despite the fact that EPA's previous risk assessments on these two chemicals identify women of childbearing age and the developing fetus as a primary susceptible population (in addition to workers). EPA's failure to identify these populations in the scopes is both contrary to law and an abuse of discretion. TSCA § 3(12) defines "potentially exposed or susceptible subpopulation" to include "a

group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance *** , such as infants, children [or] pregnant women." 15 US.C. § 2602(12). Here, EPA has previously found that "women of childbearing age" are at greater risk of adverse health effects from these chemicals. 82 Fed. Reg. 7432, 7434 (Jan. 19, 2017); 82 Fed. Reg. 7464, 7467 (Jan. 19, 2017).

Furthermore, TSCA requires that EPA identify "the potentially exposed or susceptible subpopulations the Administrator expects to consider" in the scopes. 15 US.C. § 2605(b)(4)(D). While EPA has considered those at greater risk due to *increased exposure* in the scopes to some extent, the agency appears to defer the process of identifying populations with *greater susceptibility* to the problem formulation or risk evaluation stage: "In developing the hazard assessment, EPA will also evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s)." *See, e.g.*, NMP, Scope at pp.36-37, Docket ID: EPA-HQ-OPPT-2016-0743; 1,4-Dioxane, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0723.

V. EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures.

The scoping documents generally acknowledge the need to analyze activities related to a chemical's distribution, but EPA will need to analyze these exposures more robustly than the scopes currently reflect. *See, e.g.*, 1,4-Dioxane, Scope at p.22, Docket ID: Docket ID: EPA-HQ-OPPT-2016-0723.

The scoping documents give little, if any, attention to potential releases and exposures resulting from accidental releases. EDF does not suggest that EPA needs to consider every possible scenario, but the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks. For example, as and after Hurricane Harvey passed through Houston, over 40 sites released toxic chemicals into the environment. *See, e.g.*, More Than 40 Sites Released Hazardous Pollutants Because of Hurricane Harvey, https://www.nytimes.com/interactive/2017/09/08/us/houston-hurricane-harvey-harzardous-chemicals.html?_r=0. Given the *known* accidental releases, the huge number of petrochemical plants and refineries in the Houston area, and the likelihood that flooding there may become more common in light of climate change, such events are clearly reasonably foreseen and hence EPA needs to give more consideration to the potential for accidental releases.

VI. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures.

Language used in the scopes suggests that EPA may inaccurately assume that people comply with all warning labels and always use personal protective equipment (PPE). EDF strongly urges EPA to consider real-world exposures reflecting the reality of the sometimes low-compliance with or non-existence of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by

either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). And absent empirical evidence establishing the extent to which people are using these measures, EPA should assume that they may not be. Indeed, EPA's need for accurate information about actual compliance is another reason to rely on its authorities under TSCA § 8 to mandate that manufacturers and processors provide that information. In addition, it bears noting that reliance on PPE as a primary measure to protect workers is counter to OSHA's Industrial Hygiene Hierarchy of Controls (HOC), a long-standing principle that prioritizes measures to eliminate or reduce the presence of a hazard in occupational settings (e.g., substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves, such as through reliance on PPE and warning labels. The HOC exemplifies the best available science for creating safe, healthful workplace environments.

As an example of a problematic reference to PPE in the scopes, in the asbestos scope, EPA stated that "[d]ermal exposure is unlikely due to glove use in the workplace." Asbestos, Scope at p.37, Docket ID: EPA-HQ-OPPT-2016-0736. But EPA cites no evidence supporting this assumption. While gloves may be used in many workplaces, EPA needs to provide evidence of the extent of such use. Among other things, EPA correctly noted earlier that "certain conditions of use, such as a mechanic changing asbestos-containing brakes, may also result in dermal exposure." *Id.* at 35. Is there any evidence that all or even most mechanics wear gloves when changing brakes? Indeed, EPA should identify mechanics as a relevant potentially exposed or susceptible subpopulation based on their exposure to brakes.

In comments EDF has submitted in these dockets, EDF previously commented on the serious limitations of labeling and PPE, as well as the importance of adherence to the hierarchy of controls to limit workplace exposures. *See, e.g.*, EDF comments at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0046, March 15, 2017; and at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052, November 21, 2016. EDF reincorporates and reiterates the points made in those comments here.

VII. EPA's decision not to examine uses addressed by its planned § 6(a) rules governing certain uses of TCE, DCM, and NMP is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses.

For Trichloroethylene (TCE), Methylene Chloride (DCM), and N-Methylpyrrolidone (NMP), EPA states that conditions of use previously examined will not be re-evaluated. TCE, Scope at p.9, Docket ID: EPA-HQ-OPPT-2016-0737; DCM, Scope at p.29, Docket ID: EPA-HQ-OPPT-2016-0742 ("This includes uses assessed in the U.S. EPA (2014a) risk assessment and therefore those uses are out of scope for the risk evaluation."); NMP, Scope at pp.20, 28, Docket ID: EPA-HQ-OPPT-2016-0743 ("This includes uses assessed in the previous EPA risk assessment (U.S. EPA, 2015) and therefore those uses are out of scope for the risk evaluation."). EPA has previously found these uses even by themselves present unreasonable risks to human health. In addition, these uses have the potential to increase the total

exposure of people to these chemicals. As a result, EPA can only reasonably exclude these uses if it finalizes the proposed rules to ban these uses. EDF strongly supports those bans for the reasons it articulated in its prior comments.

If EPA does not finalize these bans, then excluding these uses is both contrary to law and arbitrary and capricious. By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses *unless* EPA has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals.

* * * * *

EDF appreciates the opportunity to provide comments and EPA's consideration of them.

Environmental Defense Fund Comments on

Ten Scopes under the Toxic Substances Control Act

Docket IDs: EPA-HQ-OPPT-2016-0725 (Pigment Violet 29), EPA-HQ-OPPT-2016-0723 (1-4, Dioxane), EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene), EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride), EPA-HQ-OPPT-2016-0735 (HBCD), EPA-HQ-OPPT-2016-0736 (Asbestos), EPA-HQ-OPPT-2016-0737 (Trichloroethylene), EPA-HQ-OPPT-2016-0741 (1-Bromopropane), EPA-HQ-OPPT-2016-0742 (Methylene Chloride), and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone)

Submitted Tuesday September 19, 2017

The Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the scopes for the risk evaluations for the first ten chemicals being evaluated under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

In addition to specific comments on each chemical, EDF is providing broad comments addressing the scopes of risk evaluations for the first 10 chemicals as well as others in the future. While our comments are broadly applicable to all of the scope documents, we include examples from specific scopes to illustrate flaws and limitations.

As explained below, these scopes deviate from certain requirements of the law and in places are too unclear and vague or ambiguous to allow us to provide definitive comments. EDF recognizes that EPA was working under tight deadlines in producing these scopes – a problem it further exacerbated by EPA's decision to make major, late changes to the risk evaluation rule. EPA should take advantage of the upcoming problem formulation stage to address the many problems we identify below, and to more clearly and transparently explain its plans for these risk evaluations.

Before discussing the merits of the scoping documents, EDF provides the following clarification about its citation approach. Each scoping document contains largely identical, boilerplate language providing the agency's overall legal approach to "conditions of use" as well as its approaches on some other issues. Indeed, each document includes the same typos or misquotes of the underlying law. For ease of reference and to reduce excessive citations, EDF quotes from the asbestos scoping document and provides simply the page number when addressing these broader legal problems that are present in each scoping document. These comments equally apply to all scoping documents since they all contain

this same language; the only difference is page number. When EDF is specifically quoting another scoping document, we provide a citation clarifying that point.

Contents:

I. TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use.

EPA's scoping documents (pp.11-13) state that EPA has determined that "certain activities may not generally be considered to be conditions of use" (p.11) and also that EPA may "exclude certain activities that EPA has determined to be conditions of use" (p.12). EPA's approach asserts that EPA is allowed to ignore numerous circumstances falling within the statutory definition of "conditions of use" and is contrary to law. For the current set of chemicals under review, EPA may well be ignoring circumstances leading to ongoing exposures, and as a result, will fail to evaluate the risks the chemicals actually pose to human health and the environment.

TSCA's language and structure unambiguously foreclose EPA's interpretation. EPA's decision to disregard certain uses and exposures is also "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to consider "factors which Congress has not intended it to consider [and] entirely fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, as the scoping documents themselves reveal, this approach leads to irrational and arbitrary applications. Instead, EPA should be guided by the statutory language and consider all of those circumstances falling within the definition of "conditions of use." EPA should evaluate all of the circumstances revealed by the evidence of use and exposure, not ignore evidence because of self-imposed blinders.

A. The plain text, overall structure, purpose, and legislative history of TSCA indicate that EPA has to determine whether a chemical substance presents an unreasonable risk comprehensively, under all of its conditions of use.

i) *The plain text requires EPA to consider all conditions of use.*

Statutory interpretation should begin, as always, with the language of the statute. The plain language of both the risk evaluation provision and the definition of conditions of use support the interpretation that EPA must consider all circumstances falling within the statutory definition of "conditions of use." The main risk evaluation provision, TSCA § 6(b)(4)(A), directs that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). Inserting the statutory definition of conditions of use, this provision provides that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* §§ 2605(b)(4)(A), 2602(4). Thus, EPA has to analyze the risks of a substance under the circumstances described in the definition of "conditions of use," and no qualifying language allows EPA to exclude circumstances within that definition. The clause "as determined by the Administrator" calls for a factual finding or determination to be made by EPA. The relevant dictionary definition of "determine" is to "ascertain or establish exactly, typically as a result of research or calculation." OXFORD

AMERICAN DICTIONARY 474 (3d ed. 2010). While EPA may exercise reasonable judgment when interpreting "reasonably foreseen," nothing in this language grants EPA discretion to *ignore* factual circumstances that fall within the definition of "conditions of use." Indeed, statutes often direct agencies "to determine" things or make "determinations," and it is understood that the agency must make the finding required by the statutory language.

EPA's position that it can ignore known and foreseeable uses violates the text of the law. In the scoping documents, EPA asserts that it may ignore "legacy uses" and "associated disposals," impurities, alleged "de minimis" exposures, intermediates, conditions of use within closed systems, and conditions of use that have been analyzed by another regulatory agency (p.12). But "conditions of use" expressly includes "the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen to be to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). And every one of those circumstances is a "known" or "reasonably foreseen" "manufacture", "process[ing]," "use," or "disposal of" a chemical substance. Congress expressly chose to define "conditions of use" broadly to include not only "intended," but also "known" or "reasonably foreseen" manufacture, processing, distribution, use, and disposal. 15 U.S.C. § 2602(4). Disregarding chemical substances present as impurities or byproducts in the scoping documents, for example, because they are not "intended" essentially reads the other two scenarios out of the statute. Similarly, all the other identified conditions of use are also "intended, known, or reasonably foreseen." For example, EPA's scope suggests that 90% of the domestic production of Pigment Violet 29 "is processed as a site-limited intermediate." Pigment Violet 29, Scope at p.19, Docket ID: EPA-HQ-OPPT-2016-0725. It would absurd to ignore these intermediate uses when analyzing this chemical; doing so will lead to a truncated and incomplete analysis. Similarly the decision to exclude 1,4-dioxane's presence in numerous consumer, commercial, and industrial products as a byproduct of ethoxylation is entirely inappropriate, and will result in deficient and erroneous evaluation and determination of the chemical substance's risks. The same points can be made for many of the other chemicals used as intermediates or present as byproducts of chemical or product manufacture.

In contrast to the correct interpretation, EPA's new interpretation finds no support in the text. In the final risk evaluation rule (82 Fed. Reg. 33,726, 33,729 (July 20, 2017)), the only statutory textual basis for EPA's theory appears to be the "expects to consider" clause in the scope provision, TSCA § 6(b)(4)(D), requiring EPA to "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator *expects to consider*." 15 U.S.C. § 2605(b)(4)(D). But "expects to consider" does not mean "chooses to consider" or "prefers to consider." It is not the language of discretion; it is temporal language of anticipation or prediction. The dictionary definition of "to expect" is to "regard (something) as likely to happen." OXFORD AMERICAN DICTIONARY 609 (3d ed. 2010). This language indicates that, in the scope, EPA should describe what it anticipates studying, but it does not state that EPA has discretion to choose to ignore intended, known, or reasonably foreseen uses, hazards, or exposures. Moreover, the provision dictating what EPA must consider during a risk evaluation does not limit EPA's analysis to conditions of use identified in the scope. 15 U.S.C. § 2605(b)(4)(F). Indeed, EPA must consider all such conditions to fulfill its requirement that EPA account for the "likely duration, intensity, frequency, and

number of exposures under the conditions, where relevant." 15 U.S.C. 2605(b)(4)(F)(iv). Thus, the statutory language does not support EPA's assertion of discretion, including EPA's decision to limit its analyses to those factors identified in each scope. For example, under the rule of the last antecedent, the phrase "the Administrator expects to consider" does not even *modify* "conditions of use" or "hazards" or "exposures." Notably, EPA has so little regard for the statutory language that it repeatedly misquotes this language in significant ways.

Textually, EPA's argument also directly conflicts with TSCA § 26(k). 15 U.S.C. § 2625(k). TSCA § 26(k) requires EPA to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." *Id.* Notably, this requirement does not include *any* conditional phrase that modifies "conditions of use." And Congress included this provision to ensure that EPA could not ignore "reasonably available" "information relating to a chemical substance or mixture"; the purpose of this provision is to compel EPA to consider all reasonably available information. It would undermine this directive if EPA chooses to arbitrarily ignore certain uses and related exposures.

ii) *TSCA's overall structure requires EPA to consider all of the conditions of use.*

TSCA provisions direct EPA to prepare risk evaluations and the related findings for "chemical substances," *as a whole*, not for specific or limited conditions of use of those substances. For example, the risk management provision expressly requires EPA to address risks when the risks arise from combined exposure. TSCA § 6(a) provides that: "If [EPA] determines in accordance with [the risk evaluation provision] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, *or that any combination of such activities*, presents an unreasonable risk of injury to health or the environment," then EPA must issue a risk management rule. 15 U.S.C. § 2605(a); *see also* 15 U.S.C. § 2608(a) (using same language in provision governing requests to other federal agencies to address risks). Thus, if "any combination" of conditions of use presents an unreasonable risk, EPA must issue a risk management rule. But EPA must analyze *all* of these activities to assess whether *any combination* presents a risk.

When describing the end of a risk evaluation, TSCA requires EPA to make a finding about the "chemical substance" with no reference to conditions of use. *See, e.g.*, 15 U.S.C. § 2605(c)(1), (*i*) ("If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A)," then EPA must issue a regulation to address the unreasonable risk.). The absence of any reference to conditions of use makes it clear that EPA must make a finding for a chemical substance as a whole, not one limited to certain conditions of use. Notably, in the final prioritization rule, EPA correctly reasoned that this type of language indicated that EPA had to consider *all* uses in prioritization. *See* 82 Fed. Reg. 33,753, 33,755 (July 20, 2017) ("The statute directs EPA to make prioritization determinations on a 'chemical substance' or 'substance,' not on 'uses,' *see, e.g.*, 15 U.S.C. §§ 2605(b)(1)(A)-(C), and in most cases, without reference to 'the conditions of use.'"). This reasoning equally applies to risk evaluations.

iii) *TSCA's purpose, as well as basic logical reasoning and the best available science, require EPA to consider all conditions of use to assess a chemical substance as a whole.*

The purpose of the risk evaluation is to analyze the risks of a substance based on an assessment of its hazards and exposures. Ignoring potential exposures at the outset undermines that purpose. And science and logic do not support EPA's exceptions. For example, EPA states that it may disregard so-called "de minimis" exposures from conditions of use that occur in a closed system or use as an intermediate (p.12). But intermediates are often not completely consumed in chemical reactions and may remain as a residual in final reaction products. *See, e.g.*, California Department of Toxic Substances Control, Spray Polyurethane Foam Systems Containing Unreacted Methylene Diphenyl Diisocyanates, http://www.dtsc.ca.gov/SCP/Spray_Polyurethane_Foam.cfm (last visited Sept. 18, 2017). So the presumption that intermediates lead to a "de minimis" exposure is often contrary to the scientific evidence. In addition, intermediates must still be manufactured as well as typically being stored, transferred, or distributed, all of which are activities that can lead to exposures – including to workers, whom TSCA expressly identifies as a "potential exposed or susceptible subpopulation." Similarly, unintended impurities or contaminants can nonetheless lead to exposures and hence risks to human health or the environment, the significance of which needs to be determined in conducting a risk evaluation. *See infra* at pp.10-11 (discussing 1,4-dioxane). Ignoring them at the outset is contrary to the purpose of TSCA and risk evaluations, as well as the law's requirement that EPA rely on the best available science.

To be sure, EDF generally agrees with EPA's statement that "all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk." 82 Fed. Reg. at 33,734. Legally, EPA may be able to provide a concise and scientifically valid finding that a particular condition of use—such as the use phase of a chemical used as an intermediate—leads to little or no exposure and risk in a particular case, based on less than an in-depth analysis. And TSCA does not require a quantitative evaluation when a qualitative evaluation is determined and documented to be appropriate. But TSCA does not authorize EPA to simply "exclude" conditions of use at the outset as a matter of legal discretion. Furthermore, EPA must provide a scientific, data-backed rationale for why it decides a less extensive evaluation is sufficient, and cannot merely rely on a lack of data for such a decision.

EPA is imposing blinders on its analysis by asserting its authority to refuse to look at certain conditions of use, including known uses and disposals, and the result is that EPA is overlooking exposures in the real world. This approach is both contrary to law and arbitrary and capricious, as explained *infra* at Part I.D.

iv) *The legislative history does not justify or even lend support to EPA's approach.*

To justify its new position, EPA has emphasized the "legislative history" (p.11). But the legislative history, read as a whole, does not support EPA's approach. In the risk evaluation rule, EPA claims that the "legislative history of the amended TSCA *** explicitly states that the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation." 40 Fed. Reg. at 33,728 (citing 114 Cong. Rec. S3519-20 (daily ed. June 7, 2016) (statement of Sen. Vitter)). EPA relies on a floor

statement from a single Senator, which is one of the least illuminating forms of legislative history. EPA ignores that the rest of the legislative history reveals that other Senators thought that the statutory language would require EPA to consider all conditions of use in risk evaluations under the Lautenberg Act. Four principal Democratic negotiators of the legislation submitted a statement to the record that: "[t]he definition of 'conditions of use' described above plainly covers all uses of a chemical substance." 114 Cong. Rec. S3516 (daily ed. June 7, 2016). Similarly, when explaining why the bill expressly "grandfathered" in prior risk assessments (such as for Methylene Chloride), these negotiators explained that the provision was necessary because those "risk assessments for these chemicals were not conducted across all conditions of use." *Id.* at S3519. This explanation clearly reflects that *future* risk evaluations under TSCA would have to be conducted "across all conditions of use."

Unlike the text and structure of TSCA, the legislative history is somewhat ambiguous at points, although, if anything, it supports the position that EPA must consider "all conditions of use" since more Senators expressed that view and they did so in a formal statement.

B. Conditions of use expressly include certain so-called legacy uses and associated disposals.

In each of the scopes EPA stated that it *will* exclude so-called "legacy uses" and "associated disposal," (p.12) and EPA appears to rely on its reasoning from the risk evaluation rule. 82 Fed. Reg. at 33,729-30. EPA has asserted that no statutory text addresses this issue, and EPA stated that the use of the phrase "to be" in the definition of "conditions of use" implies a prospective application. 82 Fed. Reg. at 33,730; *see* 15 U.S.C. § 2602(4) (defining conditions of use to "mean[] the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen *to be* manufactured, processed, distributed in commerce, used, or disposed of") (emphasis added). EPA also (inaccurately) asserted that it did "not have an effective tool to address risks found to arise from uses in consumer settings if there" is no on-going manufacture, processing, or distribution. 82 Fed. Reg. at 33,730. But none of this reasoning survives scrutiny.

EPA's argument based on tense clearly does not apply to the legacy uses and associated disposals. If a chemical substance is present in a product or material that an industrial, commercial, or residential consumer is still using, then the substance is known "to be" used in that circumstance. Similarly, if a substance has not been disposed of yet, its disposal is in the future and reasonably foreseeable. As a result, these "legacy uses" and "associated disposal[s]" fall squarely within TSCA's definition of "conditions of use," which includes the "circumstances *** under which a chemical substance is *** known *** to be *** used, or disposed of." 15 U.S.C. § 2602(4). EPA has presented no textual basis for treating the first three participles in the list in this definition (manufactured, processed, and distributed in commerce) differently than the last two participles (used and disposed of).

EPA's theory that § 6 focuses on the "continuing flow of chemical substances" in "their lifecycles" (p.12) completely ignores that the use and disposal of a chemical is *part* of the lifecycle of a chemical, as defined by Congress in TSCA. Indeed, chemicals that are still in use are still "distributed in commerce" as that term is defined in TSCA. 15 U.S.C. § 2602(5). In the final risk evaluation rule, EPA stated that it

"believes the statute is better interpreted to focus on the prospective flow of the chemical substance," 80 Fed. Reg. at 33,730, but Congress expressly covered substances *after* their introduction into commerce as well.

EPA also justified its decision to ignore legacy uses by claiming it lacks tools to address risks from uses in consumer settings if there is no on-going commercial manufacture, processing, or distribution. 80 Fed. Reg. at 33,730. But TSCA § 6(a) expressly provides EPA with authorities that could manage some of these risks, even if it does not provide as broad authority as it does over manufacturers and processors. *See* 15 U.S.C. § 2605(a). For example, at risk management, EPA may impose "[a] requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture." *Id.* § 2605(a)(5). For example, EPA could ban the sale or future use of products containing a chemical even if that chemical is no longer in production in the United States, or EPA could require that such items be labeled. EPA may also impose "[a] requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or *by any other person* who uses, or disposes of, it for commercial purposes." *Id.* § 2605(a)(6)(A) (emphasis added).

In any event, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Indeed, in order to assess real-world risks of a chemical using the best available science, EPA needs to consider even those exposures over which it has limited or shared control. This approach is particularly appropriate given TSCA § 9's referral provisions.

C. The text and overall structure of TSCA makes it clear that EPA has to analyze uses, even if they have been assessed by another agency or are within another agency's jurisdiction.

EPA also stated that it may "exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risk" (p.12). But EPA provides no textual basis for ignoring those uses, which are often "circumstances *** under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Nothing in the risk evaluation provision or definition of conditions of use authorizes EPA to ignore conditions of use because of other agencies' jurisdiction over chemical substances. And several other provisions of TSCA indicate that Congress intended for EPA to consider such exposures, except to the extent Congress explicitly provided otherwise.

First, TSCA § 9(a) provides a detailed procedural mechanism for EPA under certain circumstances to request for another federal agency to address an unreasonable risk arising from a chemical substance that EPA has identified. 15 U.S.C. § 2608(a). This request then triggers a number of duties for both EPA and the other agency, requiring one of the two agencies to take action to address the risk. Thus Congress intended for EPA to prepare risk evaluations analyzing uses that might be addressed by another agency, and Congress created a substantive and procedural mechanism to resolve overlapping jurisdiction only *after* completing the risk evaluation. If EPA could just ignore risks arising from

conditions of use that fall within other agencies' jurisdiction, or if Congress meant for EPA to defer to those agencies' current regulatory approach to those chemicals at the outset before conducting a risk evaluation, then EPA might never make the finding that triggers the § 9(a) process. Here again, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Given that Congress expressly addressed the issue of overlapping regulatory jurisdictions in TSCA § 9, EPA cannot avoid those procedures by simply ignoring uses that fall within another agency's jurisdiction. Furthermore, EPA is expressly required to evaluate exposures from combinations of activities, which it cannot do if it excludes conditions of use at the outset that have been evaluated or regulated by another agency, particularly when that risk management is not an outright ban.

Second, Congress expressly exempted certain regulated chemicals or uses of chemicals from EPA's authority when it defined "chemical substance" in TSCA § 3(2). 15 U.S.C. § 2602(2)(B). For example, "chemical substance" does not include certain materials as defined in the Atomic Energy Act of 1954. *See id.* § 2602(2)(B)(ii), (iv). Thus, when Congress intended for EPA not to regulate certain conditions of use because they were regulated under other specific federal statutes, Congress expressly excluded those conditions of use. That Congress chose a limited, specific set of exclusions indicates that Congress did not intend for EPA generally to ignore other conditions of use even where they fall under other federal regulatory schemes.

D. The scopes contain incoherent and arbitrary and capricious reasoning because of EPA's approach to conditions of use.

EPA's illegal approach to "conditions of use" leads it to put "blinders" on regarding certain uses, exposures, and risks. The result is "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to have considered "factors which Congress has not intended it to consider [and] entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. It also violates several provisions of TSCA § 26 because by ignoring uses, exposures, and related information, EPA will not be acting "consistent with the best available science," EPA will not base decisions on "on the weight of the scientific evidence," and EPA will not "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h), (*i*), (k). In addition, because EPA's distinction is a false one untethered to the information, EPA seems to treat certain conditions of use inconsistently throughout the documents.

For example, in the 1,4-dioxane scope, EPA states that it will not consider risks arising from 1,4-dioxane when it is present as a by-product or residual contaminant from the manufacture of other chemicals. *See* 1,4-Dioxane, Scope at p.21, Docket ID: EPA-HQ-OPPT-2016-0723. But EPA identifies numerous products that "potentially contain[] 1,4-dioxane as a residual contaminant, including paints, coatings, lacquers, ethylene glycol-based antifreeze coolants, spray polyurethane foam, household detergents, cosmetics/toiletries, textile dyes, pharmaceuticals, foods, agricultural and veterinary products," as well as "magnetic tape and adhesives." *Id.* These are known and reasonably foreseen conditions of use

leading to exposures to 1,4-dioxane, and EPA's decision to ignore them when analyzing whether this chemical presents an unreasonable risk is arbitrary and capricious. EPA's theory is that it cannot regulate these impurities until it analyzes ethoxylated chemicals (*id.* at 8), but EPA provides no reasoned legal theory for why it could not act to regulate these exposures after this risk evaluation. *Id.* Even more problematically, EPA staked out the position that "EPA may choose not to include a particular impurity within the scope of any risk evaluation." 82 Fed. Reg. at 33,730. So these exposures may never be analyzed.

In addition, EPA acknowledges that 1,4-dioxane is often used as an intermediate or a reactant and that "the 1,4-dioxane would react either fully *or to a lesser extent*. Following completion of the reaction, the produced substance *may or may not be purified further*, thus removing unreacted 1,4-dioxane (if any exists). Reacted 1,4-dioxane is *assumed* to be destroyed and is thus not expected to be released or cause potential worker exposures." *See* 1,4-Dioxane, Scope at p.56, Docket ID: EPA-HQ-OPPT-2016-0723 (emphases added). But EPA never acknowledges that the unreacted 1,4-dioxane could lead to exposure. And that document provides no explanation, documentation, or quantification supporting the underlying assumption that 1,4-dioxane is destroyed or reacted. Indeed, from the description, it seems clear that it often will not be destroyed. The assumption in the last quoted sentence is contrary to the statements made in the proceeding sentences.

EPA's scopes should indicate that it will assess the reasonably available information on hazards and exposures for the substances (see Section II below), and that information should inform EPA's evaluation of the risks associated with "the conditions of use." If there is a real-world exposure, then EPA should not ignore it.

II. EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA §§ 4 and 8 to obtain additional information.

TSCA orders EPA to consider "available" and "reasonably available" information in crafting a risk evaluation, 15 U.S.C. §§ 2605(b)(4)(F)(i), 2625(k), and under the new risk evaluation rule, EPA defined "[r]easonably available information" to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 C.F.R. § 702.33, promulgated at 82 Fed. Reg. 33,748 (July 20, 2017). Thus, under its own rule, EPA has to consider information that it "can reasonably generate, obtain, and synthesize."

Yet, the scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is *reasonably* available information.

A. Any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities.

EPA must promulgate reasonable regulations under § 8(d) and 8(a) to obtain information about hazards, exposures, and conditions of use for these ten chemicals; EPA should also exercise its authority under § 8(c) to obtain additional information. Consistent with TSCA § 8(a)(5), EPA can take steps to reduce unnecessary and duplicative reporting. Because TSCA requires EPA to produce robust risk evaluations that reflect "reasonably available" information, and information available under these authorities is "reasonably available" on its face, EPA must use these authorities to fulfill its duty. Moreover, these first ten risk evaluations are crucial to establishing the credibility of the TSCA program under the Lautenberg Act, and EPA can only establish that credibility by using its full authority to obtain "reasonably available information" on chemicals, as required by the law. Collecting this information is also necessary to fulfill EPA's duty to use the best available science under TSCA § 26.

TSCA § 8(d) allows EPA to "require any person who manufactures, processes, or distributes in commerce *** any chemical substance or mixture *** to submit to the Administrator—lists of health and safety studies: (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person; or (C) reasonably ascertainable by such person." 15 U.S.C. § 2607(d). EPA should issue § 8(d) rules for these ten chemicals. To obtain a complete picture, EPA should expressly require both manufacturers and processors to report on these chemicals under the § 8(d) rules. *See* 40 C.F.R. § 716.5(c).

EPA has previously issued such rules for some of these chemicals, but two decades have passed since the last of those rules sunsetted, so new, additional health and safety studies are almost certainly available. For example, the methylene chloride and asbestos reporting periods sunsetted in 1992, the HBCD reporting period sunsetted in 1995, and the perchloroethylene reporting period sunsetted in 1997. *See* 40 C.F.R. § 716.120. Given scientific advancement over the last two decades, issuing new rules calling in health and safety studies would likely provide EPA with additional valuable information to assess the hazards, exposures, and risks posed by these chemicals. It appears that EPA has never issued such rules for Carbon Tetrachloride, Trichloroethylene, Pigment Violet 29, 1-Bromopane, 1-4 Dioxane, and N-Methylpyrrolidone. *See* 40 C.F.R. § 716.120. Thus, issuing § 8(d) rules for those chemicals is even more important.

Notably, EPA's regulations correctly interpret "health and safety study" broadly to incorporate "[a]ny data that bear on the effects of a chemical substance on health or the environment." 40 C.F.R. § 716.3. These include numerous tests for health and environmental effects. *See id.* They also include monitoring data and other assessments of human and environmental exposures. *See id.* EPA should also review these studies upon receipt and request underlying data under 40 C.F.R. §§ 716.10(a)(4), 716.40(a). EPA should also separately request reporting on these chemicals when they are manufactured, processed, or distributed as an impurity, 40 C.F.R. § 716.20(a)(9), because impurities may be an important source of exposure and thus risk, as explained above.

Under TSCA § 8(a), EPA may require manufacturers and processors to provide extensive information. *See* 15 U.S.C. § 2607(a)(2). EPA "shall, to the extent feasible" "not require reporting which is unnecessary or duplicative" and also "apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title." *Id.* § 2607(a)(5). To avoid duplication, EPA need not request reporting on information EPA has already obtained through other recent submissions such as through the Chemical Data Reporting (CDR) process. *See* 40 C.F.R. Part 711. But the CDR process does not require manufacturers and processors to provide all information that EPA can reasonably obtain under TSCA § 8(a) which is relevant to the risk evaluations. For example, EPA should require reporting of: "[a]ll existing information concerning the environmental and health effects of" each chemical; "the byproducts resulting from the manufacture, processing, use, or disposal of each" chemical; more detailed information about exposures to these chemicals, including the duration, frequency, and timing of exposures; and additional information about disposal. *See* 15 U.S.C. § 2607(a)(2). In particular, EPA can require submission of any data available on releases or exposures in the workplace and environment, and those data would be crucially important to an accurate risk evaluation. To decrease the burden on industry, EPA should pursue both rulemakings simultaneously, and EPA can provide that when information is submitted under one rule, the same information need not be submitted under the other. But EPA should use both authorities to ensure that it does not miss any information that may fall within one authority but not the other.

In addition, EPA should rely on its request authority under TSCA § 8(c). Under TSCA § 8(c), "[a]ny person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture." 15 U.S.C. § 2607(c). EPA promulgated rules governing this recordkeeping requirement at 40 C.F.R. Part 717. The rules apply to most manufacturers and many processors. 40 C.F.R. § 717.5. Manufacturers and processors must maintain records of many types of allegations, as detailed in 40 C.F.R. §§ 717.5 and 717.10. The regulation defines "significant adverse reactions" to include, but not be limited to, many specific types of harm that are highly relevant to the ultimate question presented in a risk evaluation: "whether a chemical substance presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(b)(4)(A). Firms must maintain these records for 30 or 5 years, depending on the circumstances. 40 C.F.R. § 717.15(d).

EPA should use its authority to request these records on alleged significant adverse reactions caused by the ten chemicals analyzed in the scope documents and add them to the administrative record for the relevant chemical. EPA can request records from manufacturers and processors that reported the chemicals in response to any § 8(a) and 8(d) rules or in response to CDR reporting. *Id.* § 717.17. EPA can request those records by letter. *Id.* § 717.17(b). Finally, EPA can also notify all people holding such records to provide them by a notice in the Federal Register. *Id.* These records may provide valuable information on hazards, exposures, and conditions of use, since the records may reveal not only significant adverse reactions but also information about the specific exposure and use that may have caused the reaction.

B. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps.

EPA should make robust use of its § 4 authority to fill any gaps in information. EDF recognizes that time constraints apply to these first ten chemicals and thus some types of testing may not be possible, but going forward, EPA needs to use its authority fully and do so in a timeframe that ensures it will have all of the information it needs to conduct risk evaluations.

As EPA moves forward on the first 10 risk evaluations, it should first clearly identify *all* significant information gaps on hazards or exposures. Based on its own regulation, EPA must then use its authority under TSCA § 4(a)(2) to require the development of new information to fill those gaps wherever possible. Information that EPA can generate under TSCA § 4(a)(2) is reasonably available under EPA's own regulation as "information that EPA *** can reasonably generate [and] obtain *** for use in risk evaluations." 40 C.F.R. § 702.33. Thus, EPA should identify such information gaps and then promptly require the conduct of all testing that can be done and still meet the statutory deadlines for the risk evaluations.

TSCA § 4(a)(2) provides that EPA "may, by rule, order, or consent agreement require the development of new information relating to a chemical substance *** if the Administrator determines that the information is necessary *** to perform a risk evaluation under section 6(b)." 15 U.S.C. § 2603(a)(2)(A)(i). Congress provided this additional testing authority allowing EPA to require testing or other data development efforts solely upon a determination "that the information is necessary *** to perform a risk evaluation under section 6(b)." *Id.* In light of deadlines, EPA can and should use its order authority and does not need to make the additional findings required for a rule under TSCA § 4(a)(1).

In places in these scopes, EPA seems to be going out of its way to avoid using its information authorities. For example, in numerous places in these scopes, with respect to exposure, EPA indicates that "[f]or conditions of use where data are limited or not available, [it will] review existing exposure models that may be applicable in estimating exposure levels" (p.43). This language suggests that EPA will simply default to models rather than use its authority to get needed information. In EDF's view, EPA should first use its authorities under TSCA §§ 8 and 4 to fill those information gaps, rather than rely on models to compensate for lack of information. This is not to say that exposure models do not have a role, but they are not a basis for avoiding the obligation to collect information.

Our review of the scopes indicates that there are significant gaps in the information. Where possible EPA needs to fill those gaps. When it is not possible, consistent with TSCA § 26, EPA needs to identify those gaps and characterize the uncertainty in the draft risk evaluations. To cite just one example, in the scope for Methylene Chloride EPA completely fails to mention an information gap earlier identified in the Work Plan. Specifically, the 2014 Work Plan Assessment for Methylene Chloride identified both developmental neurotoxicity and immunotoxicity from chronic exposure as important data gaps, impacting the selection of the point of departure:

> There is uncertainty about chronic exposure impacts on the nervous system function. The nervous system has been well studied and identified as very sensitive for acute effects. However, there is a paucity of data on chronic neurological impacts, especially developmental neurotoxicity. Likewise, there is limited information about immunotoxicity following chronic exposure to DCM. Existing hazard studies are not sufficient for dose response analysis to provide a lower point of departure than existing adverse findings in the liver from chronic exposures."

See Methylene Chloride: Paint Stripping Use, TSCA Work Plan Chemical Risk Assessment at p.115, https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf

C. If EPA already has relevant information, it is reasonably available and EPA should consider it.

The strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." *See, e.g.*, Asbestos literature at p.13. But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation *** is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available, EPA must review it.

In addition, much of this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. First, historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act. Second, the Lautenberg Act greatly increased the requirements companies must meet to assert CBI claims. For example, information only qualifies for protection if the submitter asserts *and* substantiates that it has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c). Thus, even if the information once merited protection, it may no longer be confidential under the standards of TSCA § 14. Third, as a general rule, TSCA § 14(b)(2) provides that health and safety studies and information from health and safety studies are not entitled to confidential treatment, so much of this information may not be confidential under that provision.

To fulfill its duties under TSCA, EPA must review this reasonably available information and identify that which is potentially relevant to the risk evaluations. Where information is relevant, EPA should also consider whether the information meets the strict requirements for nondisclosure under TSCA § 14. If not, EPA should add it to the administrative record for review by the public. Whether or not it meets those requirements, EPA should then determine whether and how to consider the information in evaluating these chemicals. Notably, TSCA § 26(j) requires that, "subject to section 14," EPA "shall make

available to the public *** a list of the studies considered by [EPA] in carrying out each such risk evaluation, along with the results of those studies." 15 U.S.C. § 2625(j).

D. When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information.

In the literature searches, EPA sometimes states that it relied on recent assessments, and then only performed research for dates beyond those assessments. *See, e.g.*, 1,4-Dioxane, Strategy for Conducting Literature Searches for 1,4-Dioxane: Supp. File for the TSCA Scope at p.7, 9-10, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0047. EPA needs to provide a short analysis presenting its review of the prior analysis to ensure it adequately captured and addressed all reasonably available information as of the date of its publication, particularly given the expanded obligations under the Lautenberg Act. If EPA finds it was not adequate, then EPA should broaden its literature search.

III. EPA needs to take additional steps to ensure both the completeness and accuracy of the information it relies upon.

As explained above, EPA should rely on its authorities under TSCA §§ 8 and 4 to obtain all reasonably available information. Those authorities include a number of measures to ensure the accuracy and completeness of the data relied upon. To the extent EPA relies on voluntarily submitted information, EPA needs to take additional steps to ensure the accuracy and completeness of the information. Otherwise, EPA will violate TSCA § 26 by failing to make decisions "in a manner consistent with the best available science." 15 U.S.C. § 2625(h)

A. EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals.

EPA has requested in each of the scopes that industry and other stakeholders provide information. While this voluntary request was a reasonable first step towards obtaining the necessary information, EPA has failed to provide any account for how this voluntary approach to collecting information will result in EPA obtaining all "reasonably available" information as EPA has defined that term. There are several obvious problems and limitations with this voluntary approach which EPA has not even acknowledged, much less addressed.

First, a voluntary call is much less likely to produce all of the necessary information than rules mandating that affected parties provide the requested information. If manufacturers and processors are legally required to provide the information, that legal obligation provides a strong incentive for them to collect and submit all relevant information. Absent that incentive, some companies may choose to focus time and attention on other matters. Indeed, the burdens (whether one considers them heavy or light) of collecting and submitting information counsel in favor of issuing mandatory rules. *If* the process of

collecting and submitting the information is not onerous or difficult, then using rules to require the submission of the information will do little if any harm to the regulated industry, and use of rules will ensure EPA has a complete picture and increase credibility. Alternatively, to the extent that the process is onerous or difficult, it is even more important that EPA *require* the submission of the information, because otherwise those burdens will likely discourage stakeholders with relevant information from collecting and submitting the information.

Second, EPA has provided no empirical evidence establishing that this voluntary approach will result in EPA obtaining all "reasonably available" information. Unless EPA has some empirical basis for stating that the voluntary approach will allow EPA to obtain all reasonably available information that it can obtain under its legal authorities, EPA must rely on its existing authorities to obtain a complete set of information.

Indeed, EPA's prior experience with voluntary reporting provides strong evidence that a voluntary approach is unlikely to provide complete and accurate data. For example, an EPA advisory committee called for the development of nanomaterial reporting rules in 2005, but EPA instead spent several years developing and carrying out a voluntary reporting program, the Nanoscale Materials Stewardship Program (NMSP). This voluntary reporting program produced minimal information as revealed by EPA's 2009 interim report on the NMSP. Nanoscale Materials Stewardship Program, Interim Report, OPPT (Jan. 2009), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0003. "[I]n the report EPA estimated that companies provided information on only about 10 percent of the chemical substances manufactured at the nanoscale that may be commercially available in 2009." 80 Fed. Reg. 18,330, 18,334 (April 6, 2015). In 2017, over a decade after the data need was identified, EPA finally finalized a § 8(a) reporting rule to acquire the data. 82 Fed. Reg. 3641 (Jan. 12, 2017). Given the past failures of voluntary approaches, EPA should not rely on them here.

Third, manufacturers and processors of these chemicals have a vested interest in EPA finding that the chemicals do not present an unreasonable risk. A no-unreasonable-risk finding reduces the likelihood of government regulation, including potential restrictions on risky chemicals, and it may reduce any stigma they may otherwise face in the marketplace. The financial costs of regulation may ultimately be very high for some specific firms and individuals, and even if not, many firms and individuals may *believe* that the costs of regulation will be high. These companies have a "financial interest" in the outcome of these proceedings, and they are not impartial. *See, e.g.*, 28 U.S.C. § 455(b)(4) (requiring Judges to disqualify themselves in proceedings where they have a financial interest). Because of this reality and appearance of partiality, relying solely on voluntary measures decreases the credibility of these risk evaluations.

Relying solely on voluntary presentation of information raises the concern that the companies or trade associations may present an incomplete or skewed picture. Companies and trade associations may choose to "cherry pick" information and provide only the information that paints their chemicals in favorable light. They may provide only summaries of information that reflect conscious and subconscious judgment calls that result in unduly favorable conclusions; and without access to the full information neither EPA nor the public can independently assess such conclusions. They may choose

not to review records robustly when the review may disclose unfavorable information. They may seek to put their best foot forward and describe the ideal scenario of use and safety measures. Or, if they have unfavorable information, they may choose not to provide any information at all and simply not participate in these proceedings.

To be sure, members of the regulated community are crucial sources of information about their chemicals' uses, hazards, and exposures, but EPA cannot simply assume that they will voluntarily disclose unfavorable or complete information about their practices and products. *See* THE FEDERALIST NO. 51 (James Madison) ("If men were angels, no government would be necessary. *** [E]xperience has taught mankind the necessity of auxiliary precautions."); *Williams v. Pennsylvania*, 136 S. Ct. 1899, 1905-06 (2016) ("Bias is easy to attribute to others and difficult to discern in oneself. *** This objective risk of bias is reflected in the due process maxim that 'no man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome.'"). Here, manufacturers and processors obviously have an interest in the outcome, and EPA must craft its procedures and approaches with that reality in mind. Requiring the submission of information is the safest approach to ensuring that these parties provide all relevant information, and that is in turn crucial to establishing and demonstrating the credibility of this process.

If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information. First, EPA can require that certain information and underlying information be provided in full, which ensures completeness. In addition, a § 8(d) rule requires that people engage in an adequate search of records. 40 C.F.R. § 716.25. Second, submitters must file certification statements by authorized officials that certify that the submitted information has been submitted in compliance with the requirements of this process. *See, e.g.*, 40 C.F.R. § 711.15(b)(1). Third, submitters often must retain records of required submissions for a period of five years, and the retention of records can help encourage accurate reporting since those records would be available should a submission latter be investigated. *See, e.g.*, 40 C.F.R. § 711.25. None of these features apply to the voluntary requests for information EPA has indicated it is relying on.

In addition, as EDF has explained in prior comments, there are numerous reasons that it is important that the public have access to full studies and the underlying information, not simply robust or other study summaries. *See, e.g.*, EDF Comments on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act, Comment at p.37, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074. Without access to full studies, the public will be challenged or unable to assess and comment on the quality of the studies used by the agency. *Id.* EDF reincorporates and reiterates the numerous points made in support of public access to the full studies here. *Id.* These points also support the importance of EPA obtaining the full studies.

B. For voluntary submissions, EPA should take additional steps to ensure completeness and accuracy and to vet information based on underlying data.

To the extent it relies on voluntary submissions, EPA can and should take additional steps to better ensure that the voluntary information it receives is accurate and complete. EPA would need to develop a far more rigorous and structured process than it currently has. For example, EPA's submission process does not appear to require anyone to certify that the information in their comments is accurate or complete to the best of their knowledge. EPA should consider approaches for vetting statements and assertions, particularly when made by entities with a financial interest in the outcome of these risk evaluations.

EPA should also request that submitters always provide full studies, as well as underlying data whenever reasonably available or obtainable. Setting aside concerns about partiality, EPA needs the underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular submission.

In addition, EPA should seek input directly from workers for manufacturers and processors, providing them an easy method to submit information on workplace practices and conditions independently from management. EPA needs to take steps to allow workers to provide input in a manner that reduces the risks of any potential retaliation from management.

To give a few specific examples from the scopes:

In the Perchloroethylene scope (also known as tetrachloroethylene or PCE), EPA cites the Vinyl Institute's comments for the fact it can be a residual or byproduct in the manufacture of other chemicals. *See* Perchloroethylene, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0732 (citing comment at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0013). That comment, in turn, contains a table claiming to summarize the approximate concentrations of Perchloroethylene in light and heavy end liquid intermediate streams yielded in the EDC/VCM process for manufacturing each of four chlorinated organic substances. The comment states that there is no residual Perchloroethylene in light liquid ends and 1.1% by typical weight in heavy liquid ends. But the comment does not provide or cite any underlying data supporting these findings. When commenters provide summary statements along these lines, EPA should give them little weight unless it also receives the underlying data to ensure that the reported results or conclusions drawn accurately reflect real-world conditions and to assess the level of certainty and scope of applicability that EPA can attribute to the results or conclusions. This point holds for all of the percentages set forth in that table, including those for the other three products.

Similar concerns arise for many of the other scopes. For example, in the Carbon Tetrachloride scope, EPA states that: "there are public comments, EPA-HQ-OPPT-2016-0733-0005 [3M] and EPA-HQ-OPPT-2016-0733-0017 [ACC], stating that carbon tetrachloride may be present in a limited number of industrial products with chlorinated ingredients at a concentration of less than 0.003% by weight." Carbon Tetrachloride, Scope at p.20, Docket ID: EPA-HQ-OPPT-2016-0733. But upon examining those

comments, they do not provide any of the underlying data or enough information to assess accuracy of the statement or the level of uncertainty that should apply to the results. The ACC comment is particularly difficult to assess. It involves multiple levels of hearsay, with ACC reporting statements that companies reported to it. Some of those companies acknowledge they are also relying on hearsay from suppliers and have not taken steps to confirm these concentrations. Those suppliers might also be relying on hearsay; it is simply not clear what the bases are for some of these values. Hearsay is, of course, particularly problematic when the statement serves the interest of the person submitting the evidence. *See, e.g.*, FED. R. EVID. P. 804(b)(5) (exception for statements against interest). As such, these concentrations arguably provide at best a "lower bound" estimate; they are not sufficient in terms of establishing that the actual concentrations are not higher. While no formal hearsay rule applies to these administrative proceedings and the hearsay evidentiary rule generally has limited applicability to technical studies and business records, it is relevant to the weight EPA should give these reported values given these circumstances. ACC does not disclose the companies providing the information, making it impossible for EPA to independently address these kinds of concerns. In addition, ACC's comment often fails to provide any clarity or detail as to how the concentrations were measured or assessed, much less provide the data underlying these claimed concentrations. The ACC comment asserts concentrations for 1,4-Dioxane, Pigment Violet 29, N-Methylpyrrolidone (NMP), Methylene Chloride (DCM), Carbon Tetrachloride, and HBCD, but for most of these concentrations, it is impossible for EPA or the public to assess whether they are accurate. For some of these concentrations, the comment states that Safety Data Sheets and Technical Data Sheets are provided with the comments, but EDF did not find any attachments with the comment containing those materials. In sum, EPA needs to scrutinize these voluntary submissions carefully and ensure access to the underlying information, which is necessary to assess the accuracy of the statements therein.

In the asbestos scoping document, EPA acknowledged that the analysis of the Chlor-Alkali industry was "primarily based on information provided by either the chlor-alkali industry or [the American Chemistry Council] and is meant to represent typical practices." *See* Asbestos, Scope at p.54, Docket ID: EPA-HQ-OPPT-2016-0736. EPA correctly recognized that EPA should "further evaluate how representative the processes witnessed at these two facilities are of processes at other plants." *Id.* at 23. EPA should take measures to ensure that its process will in fact accurately assess the full range of existing practices, relying on independent data where possible. Where independent data are unavailable, EPA should reach out to workers directly to better determine actual practices. Even when companies have good practices on paper, those practices may not be the reality on the ground.

EPA also needs to carefully scrutinize statements to ensure it correctly interprets them.

IV. These scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations.

Broadly viewed, the scopes do not meet several of the statutory requirements of TSCA. TSCA § 6(b)(4)(D) requires that EPA "shall, not later than 6 months after the initiation of a risk evaluation,

publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D). These scopes do not fully satisfy these requirements. Some aspects are plainly illegal under *any* interpretation of the statute, for the reasons given above, such as the statement that "EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11).[1] But many other aspects, while problematic, can be resolved by EPA in the next step: its development of problem formulations.

It is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. EDF believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified. With respect to susceptible populations, EPA should consider workers and, in most cases, pregnant women and children, to be potentially exposed or susceptible subpopulations. We identify below a number of specific examples where EPA's scopes are unclear and merit further study.

A. 1,4-Dioxane

EPA states: "EPA evaluated the weight of the evidence for cancer in humans and animals and concluded that 1,4-dioxane is 'likely to be carcinogenic to humans' based on evidence of carcinogenicity in several 2-year bioassays." 1,4-Dioxane, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0723. However, certain language in this section suggests that EPA may not include cancer as a hazard endpoint in the risk evaluation.

Indeed, EPA almost seems to suggest that inconclusive evidence regarding the "mode of action by which 1,4-dioxane produces liver, nasal, peritoneal (mesotheliomas) and mammary gland tumors" might form a basis for disregarding the evidence of such hazards. *Id.* at 35. As a general matter, EPA should not exclude observed hazards simply because the underlying MOA is not fully delineated or understood, doing so would significantly and inappropriately jeopardize the robustness and health-protections of the risk evaluation. If there is evidence of hazard, EPA should include it in the risk evaluation, even if the precise mode of action is not yet understood.

[1] As explained above, EPA puts too much weight on a floor statement from a single Senator, David Vitter. But even Senator Vitter stated that EPA must consider all conditions of use identified in the scope. *See* 114 Cong. Rec. S3520 (daily ed. June 7, 2016) (statement of Sen. Vitter). Despite that statement, the scoping documents all state that "during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11). Thus, EPA is inconsistent in how much weight it gives to Senator Vitter's statements, and EPA's current interpretation appears to contradict the views expressed throughout the legislative history by every single legislator. If EPA excluded uses identified in the scope, such as uses in the chlor-alkali industry (e.g., pp.20, 23-24), then EPA will be acting contrary to Senator Vitter's statement.

B. Perchloroethylene

The scope for Perchloroethylene states that "EPA expects to consider hazards identified in the recent assessment by the EPA Integrated Risk Information System (IRIS) Program: neurotoxicity, kidney toxicity, liver toxicity, developmental and reproductive toxicity and cancer. Support for an association with immune and blood effects was less well characterized." Perchloroethylene, Scope at p.11, Docket ID: EPA-HQ-OPPT-2016-0732. It is unclear from the scope whether EPA intends to include immune and blood effects in particular.

C. Trichloroethylene (TCE)

In the scope for TCE, EPA suggests that TCE's use as a spot remover will not be analyzed because it was previously analyzed in a risk evaluation. TCE, Scope at p.25, Docket ID: EPA-HQ-OPPT-2016-0737. That approach may be reasonable if EPA finalizes its proposed ban on this use of TCE to address those risks, as discussed more below. But that approach only applies to those spot remover uses that have previously been analyzed, specifically commercial dry cleaning facilities. This risk evaluation needs to consider TCE's use as a consumer spot remover. Those uses have not been analyzed in-depth, and the 2014 work plan assessment recognized that some such products may contain TCE as a main ingredient. *See* Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses, TSCA Work Plan Chemical Risk Assessment at p.52, https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

D. N-Methylpyrrolidone (NMP)

The NMP scope has numerous inconsistencies with respect to its identification of the endpoints to be assessed. EPA begins by acknowledging that a "number of human health hazards have been identified for NMP including adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems." N-Methylpyrrolidone, Scope at p.36, Docket ID: EPA-HQ-OPPT-2016-0743. EPA also states that: "EPA expects to consider all potential hazards associated with NMP." *Id.* EDF completely agrees with that approach. However, the description under section 2.42 Human Health Hazards indicates that EPA intends to focus on a narrower set of hazards (acute toxicity and reproductive/developmental toxicity), and provides no justification or even explanation for excluding some of the hazards that it previously identified.

E. Potentially exposed or susceptible subpopulations

EPA also does not identify pregnant women, women of childbearing age, or the developing fetus as potential exposed or susceptible subpopulations for either N-Methylpyrrolidone (NMP) [NMP, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0743] or TCE [TCE, Scope at pp.37-38, Docket ID: EPA-HQ-OPPT-2016-0737], despite the fact that EPA's previous risk assessments on these two chemicals identify women of childbearing age and the developing fetus as a primary susceptible population (in addition to workers). EPA's failure to identify these populations in the scopes is both contrary to law and an abuse of discretion. TSCA § 3(12) defines "potentially exposed or susceptible subpopulation" to include "a

group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance *** , such as infants, children [or] pregnant women." 15 US.C. § 2602(12). Here, EPA has previously found that "women of childbearing age" are at greater risk of adverse health effects from these chemicals. 82 Fed. Reg. 7432, 7434 (Jan. 19, 2017); 82 Fed. Reg. 7464, 7467 (Jan. 19, 2017).

Furthermore, TSCA requires that EPA identify "the potentially exposed or susceptible subpopulations the Administrator expects to consider" in the scopes. 15 US.C. § 2605(b)(4)(D). While EPA has considered those at greater risk due to *increased exposure* in the scopes to some extent, the agency appears to defer the process of identifying populations with *greater susceptibility* to the problem formulation or risk evaluation stage: "In developing the hazard assessment, EPA will also evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s)." *See, e.g.*, NMP, Scope at pp.36-37, Docket ID: EPA-HQ-OPPT-2016-0743; 1,4-Dioxane, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0723.

V. EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures.

The scoping documents generally acknowledge the need to analyze activities related to a chemical's distribution, but EPA will need to analyze these exposures more robustly than the scopes currently reflect. *See, e.g.*, 1,4-Dioxane, Scope at p.22, Docket ID: Docket ID: EPA-HQ-OPPT-2016-0723.

The scoping documents give little, if any, attention to potential releases and exposures resulting from accidental releases. EDF does not suggest that EPA needs to consider every possible scenario, but the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks. For example, as and after Hurricane Harvey passed through Houston, over 40 sites released toxic chemicals into the environment. *See, e.g.*, More Than 40 Sites Released Hazardous Pollutants Because of Hurricane Harvey, https://www.nytimes.com/interactive/2017/09/08/us/houston-hurricane-harvey-harzardous-chemicals.html?_r=0. Given the *known* accidental releases, the huge number of petrochemical plants and refineries in the Houston area, and the likelihood that flooding there may become more common in light of climate change, such events are clearly reasonably foreseen and hence EPA needs to give more consideration to the potential for accidental releases.

VI. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures.

Language used in the scopes suggests that EPA may inaccurately assume that people comply with all warning labels and always use personal protective equipment (PPE). EDF strongly urges EPA to consider real-world exposures reflecting the reality of the sometimes low-compliance with or non-existence of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by

either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). And absent empirical evidence establishing the extent to which people are using these measures, EPA should assume that they may not be. Indeed, EPA's need for accurate information about actual compliance is another reason to rely on its authorities under TSCA § 8 to mandate that manufacturers and processors provide that information. In addition, it bears noting that reliance on PPE as a primary measure to protect workers is counter to OSHA's Industrial Hygiene Hierarchy of Controls (HOC), a long-standing principle that prioritizes measures to eliminate or reduce the presence of a hazard in occupational settings (e.g., substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves, such as through reliance on PPE and warning labels. The HOC exemplifies the best available science for creating safe, healthful workplace environments.

As an example of a problematic reference to PPE in the scopes, in the asbestos scope, EPA stated that "[d]ermal exposure is unlikely due to glove use in the workplace." Asbestos, Scope at p.37, Docket ID: EPA-HQ-OPPT-2016-0736. But EPA cites no evidence supporting this assumption. While gloves may be used in many workplaces, EPA needs to provide evidence of the extent of such use. Among other things, EPA correctly noted earlier that "certain conditions of use, such as a mechanic changing asbestos-containing brakes, may also result in dermal exposure." *Id.* at 35. Is there any evidence that all or even most mechanics wear gloves when changing brakes? Indeed, EPA should identify mechanics as a relevant potentially exposed or susceptible subpopulation based on their exposure to brakes.

In comments EDF has submitted in these dockets, EDF previously commented on the serious limitations of labeling and PPE, as well as the importance of adherence to the hierarchy of controls to limit workplace exposures. *See, e.g.*, EDF comments at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0046, March 15, 2017; and at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052, November 21, 2016. EDF reincorporates and reiterates the points made in those comments here.

VII. EPA's decision not to examine uses addressed by its planned § 6(a) rules governing certain uses of TCE, DCM, and NMP is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses.

For Trichloroethylene (TCE), Methylene Chloride (DCM), and N-Methylpyrrolidone (NMP), EPA states that conditions of use previously examined will not be re-evaluated. TCE, Scope at p.9, Docket ID: EPA-HQ-OPPT-2016-0737; DCM, Scope at p.29, Docket ID: EPA-HQ-OPPT-2016-0742 ("This includes uses assessed in the U.S. EPA (2014a) risk assessment and therefore those uses are out of scope for the risk evaluation."); NMP, Scope at pp.20, 28, Docket ID: EPA-HQ-OPPT-2016-0743 ("This includes uses assessed in the previous EPA risk assessment (U.S. EPA, 2015) and therefore those uses are out of scope for the risk evaluation."). EPA has previously found these uses even by themselves present unreasonable risks to human health. In addition, these uses have the potential to increase the total

exposure of people to these chemicals. As a result, EPA can only reasonably exclude these uses if it finalizes the proposed rules to ban these uses. EDF strongly supports those bans for the reasons it articulated in its prior comments.

If EPA does not finalize these bans, then excluding these uses is both contrary to law and arbitrary and capricious. By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses *unless* EPA has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals.

* * * * *

EDF appreciates the opportunity to provide comments and EPA's consideration of them.

Environmental Defense Fund Comments on

Ten Scopes under the Toxic Substances Control Act

Docket IDs: EPA-HQ-OPPT-2016-0725 (Pigment Violet 29), EPA-HQ-OPPT-2016-0723 (1-4, Dioxane), EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene), EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride), EPA-HQ-OPPT-2016-0735 (HBCD), EPA-HQ-OPPT-2016-0736 (Asbestos), EPA-HQ-OPPT-2016-0737 (Trichloroethylene), EPA-HQ-OPPT-2016-0741 (1-Bromopropane), EPA-HQ-OPPT-2016-0742 (Methylene Chloride), and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone)

Submitted Tuesday September 19, 2017

The Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the scopes for the risk evaluations for the first ten chemicals being evaluated under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

In addition to specific comments on each chemical, EDF is providing broad comments addressing the scopes of risk evaluations for the first 10 chemicals as well as others in the future. While our comments are broadly applicable to all of the scope documents, we include examples from specific scopes to illustrate flaws and limitations.

As explained below, these scopes deviate from certain requirements of the law and in places are too unclear and vague or ambiguous to allow us to provide definitive comments. EDF recognizes that EPA was working under tight deadlines in producing these scopes – a problem it further exacerbated by EPA's decision to make major, late changes to the risk evaluation rule. EPA should take advantage of the upcoming problem formulation stage to address the many problems we identify below, and to more clearly and transparently explain its plans for these risk evaluations.

Before discussing the merits of the scoping documents, EDF provides the following clarification about its citation approach. Each scoping document contains largely identical, boilerplate language providing the agency's overall legal approach to "conditions of use" as well as its approaches on some other issues. Indeed, each document includes the same typos or misquotes of the underlying law. For ease of reference and to reduce excessive citations, EDF quotes from the asbestos scoping document and provides simply the page number when addressing these broader legal problems that are present in each scoping document. These comments equally apply to all scoping documents since they all contain

this same language; the only difference is page number. When EDF is specifically quoting another scoping document, we provide a citation clarifying that point.

Contents:

I. TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use.

EPA's scoping documents (pp.11-13) state that EPA has determined that "certain activities may not generally be considered to be conditions of use" (p.11) and also that EPA may "exclude certain activities that EPA has determined to be conditions of use" (p.12). EPA's approach asserts that EPA is allowed to ignore numerous circumstances falling within the statutory definition of "conditions of use" and is contrary to law. For the current set of chemicals under review, EPA may well be ignoring circumstances leading to ongoing exposures, and as a result, will fail to evaluate the risks the chemicals actually pose to human health and the environment.

TSCA's language and structure unambiguously foreclose EPA's interpretation. EPA's decision to disregard certain uses and exposures is also "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to consider "factors which Congress has not intended it to consider [and] entirely fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, as the scoping documents themselves reveal, this approach leads to irrational and arbitrary applications. Instead, EPA should be guided by the statutory language and consider all of those circumstances falling within the definition of "conditions of use." EPA should evaluate all of the circumstances revealed by the evidence of use and exposure, not ignore evidence because of self-imposed blinders.

A. The plain text, overall structure, purpose, and legislative history of TSCA indicate that EPA has to determine whether a chemical substance presents an unreasonable risk comprehensively, under all of its conditions of use.

i) *The plain text requires EPA to consider all conditions of use.*

Statutory interpretation should begin, as always, with the language of the statute. The plain language of both the risk evaluation provision and the definition of conditions of use support the interpretation that EPA must consider all circumstances falling within the statutory definition of "conditions of use." The main risk evaluation provision, TSCA § 6(b)(4)(A), directs that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). Inserting the statutory definition of conditions of use, this provision provides that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* §§ 2605(b)(4)(A), 2602(4). Thus, EPA has to analyze the risks of a substance under the circumstances described in the definition of "conditions of use," and no qualifying language allows EPA to exclude circumstances within that definition. The clause "as determined by the Administrator" calls for a factual finding or determination to be made by EPA. The relevant dictionary definition of "determine" is to "ascertain or establish exactly, typically as a result of research or calculation." OXFORD

AMERICAN DICTIONARY 474 (3d ed. 2010). While EPA may exercise reasonable judgment when interpreting "reasonably foreseen," nothing in this language grants EPA discretion to *ignore* factual circumstances that fall within the definition of "conditions of use." Indeed, statutes often direct agencies "to determine" things or make "determinations," and it is understood that the agency must make the finding required by the statutory language.

EPA's position that it can ignore known and foreseeable uses violates the text of the law. In the scoping documents, EPA asserts that it may ignore "legacy uses" and "associated disposals," impurities, alleged "de minimis" exposures, intermediates, conditions of use within closed systems, and conditions of use that have been analyzed by another regulatory agency (p.12). But "conditions of use" expressly includes "the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen to be to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). And every one of those circumstances is a "known" or "reasonably foreseen" "manufacture", "process[ing]," "use," or "disposal of" a chemical substance. Congress expressly chose to define "conditions of use" broadly to include not only "intended," but also "known" or "reasonably foreseen" manufacture, processing, distribution, use, and disposal. 15 U.S.C. § 2602(4). Disregarding chemical substances present as impurities or byproducts in the scoping documents, for example, because they are not "intended" essentially reads the other two scenarios out of the statute. Similarly, all the other identified conditions of use are also "intended, known, or reasonably foreseen." For example, EPA's scope suggests that 90% of the domestic production of Pigment Violet 29 "is processed as a site-limited intermediate." Pigment Violet 29, Scope at p.19, Docket ID: EPA-HQ-OPPT-2016-0725. It would absurd to ignore these intermediate uses when analyzing this chemical; doing so will lead to a truncated and incomplete analysis. Similarly the decision to exclude 1,4-dioxane's presence in numerous consumer, commercial, and industrial products as a byproduct of ethoxylation is entirely inappropriate, and will result in deficient and erroneous evaluation and determination of the chemical substance's risks. The same points can be made for many of the other chemicals used as intermediates or present as byproducts of chemical or product manufacture.

In contrast to the correct interpretation, EPA's new interpretation finds no support in the text. In the final risk evaluation rule (82 Fed. Reg. 33,726, 33,729 (July 20, 2017)), the only statutory textual basis for EPA's theory appears to be the "expects to consider" clause in the scope provision, TSCA § 6(b)(4)(D), requiring EPA to "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator *expects to consider*." 15 U.S.C. § 2605(b)(4)(D). But "expects to consider" does not mean "chooses to consider" or "prefers to consider." It is not the language of discretion; it is temporal language of anticipation or prediction. The dictionary definition of "to expect" is to "regard (something) as likely to happen." OXFORD AMERICAN DICTIONARY 609 (3d ed. 2010). This language indicates that, in the scope, EPA should describe what it anticipates studying, but it does not state that EPA has discretion to choose to ignore intended, known, or reasonably foreseen uses, hazards, or exposures. Moreover, the provision dictating what EPA must consider during a risk evaluation does not limit EPA's analysis to conditions of use identified in the scope. 15 U.S.C. § 2605(b)(4)(F). Indeed, EPA must consider all such conditions to fulfill its requirement that EPA account for the "likely duration, intensity, frequency, and

number of exposures under the conditions, where relevant." 15 U.S.C. 2605(b)(4)(F)(iv). Thus, the statutory language does not support EPA's assertion of discretion, including EPA's decision to limit its analyses to those factors identified in each scope. For example, under the rule of the last antecedent, the phrase "the Administrator expects to consider" does not even *modify* "conditions of use" or "hazards" or "exposures." Notably, EPA has so little regard for the statutory language that it repeatedly misquotes this language in significant ways.

Textually, EPA's argument also directly conflicts with TSCA § 26(k). 15 U.S.C. § 2625(k). TSCA § 26(k) requires EPA to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." *Id.* Notably, this requirement does not include *any* conditional phrase that modifies "conditions of use." And Congress included this provision to ensure that EPA could not ignore "reasonably available" "information relating to a chemical substance or mixture"; the purpose of this provision is to compel EPA to consider all reasonably available information. It would undermine this directive if EPA chooses to arbitrarily ignore certain uses and related exposures.

ii) *TSCA's overall structure requires EPA to consider all of the conditions of use.*

TSCA provisions direct EPA to prepare risk evaluations and the related findings for "chemical substances," *as a whole*, not for specific or limited conditions of use of those substances. For example, the risk management provision expressly requires EPA to address risks when the risks arise from combined exposure. TSCA § 6(a) provides that: "If [EPA] determines in accordance with [the risk evaluation provision] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, *or that any combination of such activities*, presents an unreasonable risk of injury to health or the environment," then EPA must issue a risk management rule. 15 U.S.C. § 2605(a); *see also* 15 U.S.C. § 2608(a) (using same language in provision governing requests to other federal agencies to address risks). Thus, if "any combination" of conditions of use presents an unreasonable risk, EPA must issue a risk management rule. But EPA must analyze *all* of these activities to assess whether *any combination* presents a risk.

When describing the end of a risk evaluation, TSCA requires EPA to make a finding about the "chemical substance" with no reference to conditions of use. *See, e.g.*, 15 U.S.C. § 2605(c)(1), (*i*) ("If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A)," then EPA must issue a regulation to address the unreasonable risk.). The absence of any reference to conditions of use makes it clear that EPA must make a finding for a chemical substance as a whole, not one limited to certain conditions of use. Notably, in the final prioritization rule, EPA correctly reasoned that this type of language indicated that EPA had to consider *all* uses in prioritization. *See* 82 Fed. Reg. 33,753, 33,755 (July 20, 2017) ("The statute directs EPA to make prioritization determinations on a 'chemical substance' or 'substance,' not on 'uses,' *see, e.g.*, 15 U.S.C. §§ 2605(b)(1)(A)-(C), and in most cases, without reference to 'the conditions of use.'"). This reasoning equally applies to risk evaluations.

iii) *TSCA's purpose, as well as basic logical reasoning and the best available science, require EPA to consider all conditions of use to assess a chemical substance as a whole.*

The purpose of the risk evaluation is to analyze the risks of a substance based on an assessment of its hazards and exposures. Ignoring potential exposures at the outset undermines that purpose. And science and logic do not support EPA's exceptions. For example, EPA states that it may disregard so-called "de minimis" exposures from conditions of use that occur in a closed system or use as an intermediate (p.12). But intermediates are often not completely consumed in chemical reactions and may remain as a residual in final reaction products. *See, e.g.*, California Department of Toxic Substances Control, Spray Polyurethane Foam Systems Containing Unreacted Methylene Diphenyl Diisocyanates, http://www.dtsc.ca.gov/SCP/Spray_Polyurethane_Foam.cfm (last visited Sept. 18, 2017). So the presumption that intermediates lead to a "de minimis" exposure is often contrary to the scientific evidence. In addition, intermediates must still be manufactured as well as typically being stored, transferred, or distributed, all of which are activities that can lead to exposures – including to workers, whom TSCA expressly identifies as a "potential exposed or susceptible subpopulation." Similarly, unintended impurities or contaminants can nonetheless lead to exposures and hence risks to human health or the environment, the significance of which needs to be determined in conducting a risk evaluation. *See infra* at pp.10-11 (discussing 1,4-dioxane). Ignoring them at the outset is contrary to the purpose of TSCA and risk evaluations, as well as the law's requirement that EPA rely on the best available science.

To be sure, EDF generally agrees with EPA's statement that "all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk." 82 Fed. Reg. at 33,734. Legally, EPA may be able to provide a concise and scientifically valid finding that a particular condition of use—such as the use phase of a chemical used as an intermediate—leads to little or no exposure and risk in a particular case, based on less than an in-depth analysis. And TSCA does not require a quantitative evaluation when a qualitative evaluation is determined and documented to be appropriate. But TSCA does not authorize EPA to simply "exclude" conditions of use at the outset as a matter of legal discretion. Furthermore, EPA must provide a scientific, data-backed rationale for why it decides a less extensive evaluation is sufficient, and cannot merely rely on a lack of data for such a decision.

EPA is imposing blinders on its analysis by asserting its authority to refuse to look at certain conditions of use, including known uses and disposals, and the result is that EPA is overlooking exposures in the real world. This approach is both contrary to law and arbitrary and capricious, as explained *infra* at Part I.D.

iv) *The legislative history does not justify or even lend support to EPA's approach.*

To justify its new position, EPA has emphasized the "legislative history" (p.11). But the legislative history, read as a whole, does not support EPA's approach. In the risk evaluation rule, EPA claims that the "legislative history of the amended TSCA *** explicitly states that the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation." 40 Fed. Reg. at 33,728 (citing 114 Cong. Rec. S3519-20 (daily ed. June 7, 2016) (statement of Sen. Vitter)). EPA relies on a floor

statement from a single Senator, which is one of the least illuminating forms of legislative history. EPA ignores that the rest of the legislative history reveals that other Senators thought that the statutory language would require EPA to consider all conditions of use in risk evaluations under the Lautenberg Act. Four principal Democratic negotiators of the legislation submitted a statement to the record that: "[t]he definition of 'conditions of use' described above plainly covers all uses of a chemical substance." 114 Cong. Rec. S3516 (daily ed. June 7, 2016). Similarly, when explaining why the bill expressly "grandfathered" in prior risk assessments (such as for Methylene Chloride), these negotiators explained that the provision was necessary because those "risk assessments for these chemicals were not conducted across all conditions of use." *Id.* at S3519. This explanation clearly reflects that *future* risk evaluations under TSCA would have to be conducted "across all conditions of use."

Unlike the text and structure of TSCA, the legislative history is somewhat ambiguous at points, although, if anything, it supports the position that EPA must consider "all conditions of use" since more Senators expressed that view and they did so in a formal statement.

B. Conditions of use expressly include certain so-called legacy uses and associated disposals.

In each of the scopes EPA stated that it *will* exclude so-called "legacy uses" and "associated disposal," (p.12) and EPA appears to rely on its reasoning from the risk evaluation rule. 82 Fed. Reg. at 33,729-30. EPA has asserted that no statutory text addresses this issue, and EPA stated that the use of the phrase "to be" in the definition of "conditions of use" implies a prospective application. 82 Fed. Reg. at 33,730; *see* 15 U.S.C. § 2602(4) (defining conditions of use to "mean[] the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen *to be* manufactured, processed, distributed in commerce, used, or disposed of") (emphasis added). EPA also (inaccurately) asserted that it did "not have an effective tool to address risks found to arise from uses in consumer settings if there" is no on-going manufacture, processing, or distribution. 82 Fed. Reg. at 33,730. But none of this reasoning survives scrutiny.

EPA's argument based on tense clearly does not apply to the legacy uses and associated disposals. If a chemical substance is present in a product or material that an industrial, commercial, or residential consumer is still using, then the substance is known "to be" used in that circumstance. Similarly, if a substance has not been disposed of yet, its disposal is in the future and reasonably foreseeable. As a result, these "legacy uses" and "associated disposal[s]" fall squarely within TSCA's definition of "conditions of use," which includes the "circumstances *** under which a chemical substance is *** known *** to be *** used, or disposed of." 15 U.S.C. § 2602(4). EPA has presented no textual basis for treating the first three participles in the list in this definition (manufactured, processed, and distributed in commerce) differently than the last two participles (used and disposed of).

EPA's theory that § 6 focuses on the "continuing flow of chemical substances" in "their lifecycles" (p.12) completely ignores that the use and disposal of a chemical is *part* of the lifecycle of a chemical, as defined by Congress in TSCA. Indeed, chemicals that are still in use are still "distributed in commerce" as that term is defined in TSCA. 15 U.S.C. § 2602(5). In the final risk evaluation rule, EPA stated that it

"believes the statute is better interpreted to focus on the prospective flow of the chemical substance," 80 Fed. Reg. at 33,730, but Congress expressly covered substances *after* their introduction into commerce as well.

EPA also justified its decision to ignore legacy uses by claiming it lacks tools to address risks from uses in consumer settings if there is no on-going commercial manufacture, processing, or distribution. 80 Fed. Reg. at 33,730. But TSCA § 6(a) expressly provides EPA with authorities that could manage some of these risks, even if it does not provide as broad authority as it does over manufacturers and processors. *See* 15 U.S.C. § 2605(a). For example, at risk management, EPA may impose "[a] requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture." *Id.* § 2605(a)(5). For example, EPA could ban the sale or future use of products containing a chemical even if that chemical is no longer in production in the United States, or EPA could require that such items be labeled. EPA may also impose "[a] requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or *by any other person* who uses, or disposes of, it for commercial purposes." *Id.* § 2605(a)(6)(A) (emphasis added).

In any event, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Indeed, in order to assess real-world risks of a chemical using the best available science, EPA needs to consider even those exposures over which it has limited or shared control. This approach is particularly appropriate given TSCA § 9's referral provisions.

C. The text and overall structure of TSCA makes it clear that EPA has to analyze uses, even if they have been assessed by another agency or are within another agency's jurisdiction.

EPA also stated that it may "exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risk" (p.12). But EPA provides no textual basis for ignoring those uses, which are often "circumstances *** under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Nothing in the risk evaluation provision or definition of conditions of use authorizes EPA to ignore conditions of use because of other agencies' jurisdiction over chemical substances. And several other provisions of TSCA indicate that Congress intended for EPA to consider such exposures, except to the extent Congress explicitly provided otherwise.

First, TSCA § 9(a) provides a detailed procedural mechanism for EPA under certain circumstances to request for another federal agency to address an unreasonable risk arising from a chemical substance that EPA has identified. 15 U.S.C. § 2608(a). This request then triggers a number of duties for both EPA and the other agency, requiring one of the two agencies to take action to address the risk. Thus Congress intended for EPA to prepare risk evaluations analyzing uses that might be addressed by another agency, and Congress created a substantive and procedural mechanism to resolve overlapping jurisdiction only *after* completing the risk evaluation. If EPA could just ignore risks arising from

conditions of use that fall within other agencies' jurisdiction, or if Congress meant for EPA to defer to those agencies' current regulatory approach to those chemicals at the outset before conducting a risk evaluation, then EPA might never make the finding that triggers the § 9(a) process. Here again, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Given that Congress expressly addressed the issue of overlapping regulatory jurisdictions in TSCA § 9, EPA cannot avoid those procedures by simply ignoring uses that fall within another agency's jurisdiction. Furthermore, EPA is expressly required to evaluate exposures from combinations of activities, which it cannot do if it excludes conditions of use at the outset that have been evaluated or regulated by another agency, particularly when that risk management is not an outright ban.

Second, Congress expressly exempted certain regulated chemicals or uses of chemicals from EPA's authority when it defined "chemical substance" in TSCA § 3(2). 15 U.S.C. § 2602(2)(B). For example, "chemical substance" does not include certain materials as defined in the Atomic Energy Act of 1954. *See id.* § 2602(2)(B)(ii), (iv). Thus, when Congress intended for EPA not to regulate certain conditions of use because they were regulated under other specific federal statutes, Congress expressly excluded those conditions of use. That Congress chose a limited, specific set of exclusions indicates that Congress did not intend for EPA generally to ignore other conditions of use even where they fall under other federal regulatory schemes.

D. The scopes contain incoherent and arbitrary and capricious reasoning because of EPA's approach to conditions of use.

EPA's illegal approach to "conditions of use" leads it to put "blinders" on regarding certain uses, exposures, and risks. The result is "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to have considered "factors which Congress has not intended it to consider [and] entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. It also violates several provisions of TSCA § 26 because by ignoring uses, exposures, and related information, EPA will not be acting "consistent with the best available science," EPA will not base decisions on "on the weight of the scientific evidence," and EPA will not "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h), (*i*), (k). In addition, because EPA's distinction is a false one untethered to the information, EPA seems to treat certain conditions of use inconsistently throughout the documents.

For example, in the 1,4-dioxane scope, EPA states that it will not consider risks arising from 1,4-dioxane when it is present as a by-product or residual contaminant from the manufacture of other chemicals. *See* 1,4-Dioxane, Scope at p.21, Docket ID: EPA-HQ-OPPT-2016-0723. But EPA identifies numerous products that "potentially contain[] 1,4-dioxane as a residual contaminant, including paints, coatings, lacquers, ethylene glycol-based antifreeze coolants, spray polyurethane foam, household detergents, cosmetics/toiletries, textile dyes, pharmaceuticals, foods, agricultural and veterinary products," as well as "magnetic tape and adhesives." *Id.* These are known and reasonably foreseen conditions of use

leading to exposures to 1,4-dioxane, and EPA's decision to ignore them when analyzing whether this chemical presents an unreasonable risk is arbitrary and capricious. EPA's theory is that it cannot regulate these impurities until it analyzes ethoxylated chemicals (*id.* at 8), but EPA provides no reasoned legal theory for why it could not act to regulate these exposures after this risk evaluation. *Id.* Even more problematically, EPA staked out the position that "EPA may choose not to include a particular impurity within the scope of any risk evaluation." 82 Fed. Reg. at 33,730. So these exposures may never be analyzed.

In addition, EPA acknowledges that 1,4-dioxane is often used as an intermediate or a reactant and that "the 1,4-dioxane would react either fully *or to a lesser extent*. Following completion of the reaction, the produced substance *may or may not be purified further*, thus removing unreacted 1,4-dioxane (if any exists). Reacted 1,4-dioxane is *assumed* to be destroyed and is thus not expected to be released or cause potential worker exposures." *See* 1,4-Dioxane, Scope at p.56, Docket ID: EPA-HQ-OPPT-2016-0723 (emphases added). But EPA never acknowledges that the unreacted 1,4-dioxane could lead to exposure. And that document provides no explanation, documentation, or quantification supporting the underlying assumption that 1,4-dioxane is destroyed or reacted. Indeed, from the description, it seems clear that it often will not be destroyed. The assumption in the last quoted sentence is contrary to the statements made in the proceeding sentences.

EPA's scopes should indicate that it will assess the reasonably available information on hazards and exposures for the substances (see Section II below), and that information should inform EPA's evaluation of the risks associated with "the conditions of use." If there is a real-world exposure, then EPA should not ignore it.

II. EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA §§ 4 and 8 to obtain additional information.

TSCA orders EPA to consider "available" and "reasonably available" information in crafting a risk evaluation, 15 U.S.C. §§ 2605(b)(4)(F)(i), 2625(k), and under the new risk evaluation rule, EPA defined "[r]easonably available information" to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 C.F.R. § 702.33, promulgated at 82 Fed. Reg. 33,748 (July 20, 2017). Thus, under its own rule, EPA has to consider information that it "can reasonably generate, obtain, and synthesize."

Yet, the scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is *reasonably* available information.

A. Any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities.

EPA must promulgate reasonable regulations under § 8(d) and 8(a) to obtain information about hazards, exposures, and conditions of use for these ten chemicals; EPA should also exercise its authority under § 8(c) to obtain additional information. Consistent with TSCA § 8(a)(5), EPA can take steps to reduce unnecessary and duplicative reporting. Because TSCA requires EPA to produce robust risk evaluations that reflect "reasonably available" information, and information available under these authorities is "reasonably available" on its face, EPA must use these authorities to fulfill its duty. Moreover, these first ten risk evaluations are crucial to establishing the credibility of the TSCA program under the Lautenberg Act, and EPA can only establish that credibility by using its full authority to obtain "reasonably available information" on chemicals, as required by the law. Collecting this information is also necessary to fulfill EPA's duty to use the best available science under TSCA § 26.

TSCA § 8(d) allows EPA to "require any person who manufactures, processes, or distributes in commerce *** any chemical substance or mixture *** to submit to the Administrator—lists of health and safety studies: (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person; or (C) reasonably ascertainable by such person." 15 U.S.C. § 2607(d). EPA should issue § 8(d) rules for these ten chemicals. To obtain a complete picture, EPA should expressly require both manufacturers and processors to report on these chemicals under the § 8(d) rules. *See* 40 C.F.R. § 716.5(c).

EPA has previously issued such rules for some of these chemicals, but two decades have passed since the last of those rules sunsetted, so new, additional health and safety studies are almost certainly available. For example, the methylene chloride and asbestos reporting periods sunsetted in 1992, the HBCD reporting period sunsetted in 1995, and the perchloroethylene reporting period sunsetted in 1997. *See* 40 C.F.R. § 716.120. Given scientific advancement over the last two decades, issuing new rules calling in health and safety studies would likely provide EPA with additional valuable information to assess the hazards, exposures, and risks posed by these chemicals. It appears that EPA has never issued such rules for Carbon Tetrachloride, Trichloroethylene, Pigment Violet 29, 1-Bromopane, 1-4 Dioxane, and N-Methylpyrrolidone. *See* 40 C.F.R. § 716.120. Thus, issuing § 8(d) rules for those chemicals is even more important.

Notably, EPA's regulations correctly interpret "health and safety study" broadly to incorporate "[a]ny data that bear on the effects of a chemical substance on health or the environment." 40 C.F.R. § 716.3. These include numerous tests for health and environmental effects. *See id.* They also include monitoring data and other assessments of human and environmental exposures. *See id.* EPA should also review these studies upon receipt and request underlying data under 40 C.F.R. §§ 716.10(a)(4), 716.40(a). EPA should also separately request reporting on these chemicals when they are manufactured, processed, or distributed as an impurity, 40 C.F.R. § 716.20(a)(9), because impurities may be an important source of exposure and thus risk, as explained above.

Under TSCA § 8(a), EPA may require manufacturers and processors to provide extensive information. *See* 15 U.S.C. § 2607(a)(2). EPA "shall, to the extent feasible" "not require reporting which is unnecessary or duplicative" and also "apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title." *Id.* § 2607(a)(5). To avoid duplication, EPA need not request reporting on information EPA has already obtained through other recent submissions such as through the Chemical Data Reporting (CDR) process. *See* 40 C.F.R. Part 711. But the CDR process does not require manufacturers and processors to provide all information that EPA can reasonably obtain under TSCA § 8(a) which is relevant to the risk evaluations. For example, EPA should require reporting of: "[a]ll existing information concerning the environmental and health effects of" each chemical; "the byproducts resulting from the manufacture, processing, use, or disposal of each" chemical; more detailed information about exposures to these chemicals, including the duration, frequency, and timing of exposures; and additional information about disposal. *See* 15 U.S.C. § 2607(a)(2). In particular, EPA can require submission of any data available on releases or exposures in the workplace and environment, and those data would be crucially important to an accurate risk evaluation. To decrease the burden on industry, EPA should pursue both rulemakings simultaneously, and EPA can provide that when information is submitted under one rule, the same information need not be submitted under the other. But EPA should use both authorities to ensure that it does not miss any information that may fall within one authority but not the other.

In addition, EPA should rely on its request authority under TSCA § 8(c). Under TSCA § 8(c), "[a]ny person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture." 15 U.S.C. § 2607(c). EPA promulgated rules governing this recordkeeping requirement at 40 C.F.R. Part 717. The rules apply to most manufacturers and many processors. 40 C.F.R. § 717.5. Manufacturers and processors must maintain records of many types of allegations, as detailed in 40 C.F.R. §§ 717.5 and 717.10. The regulation defines "significant adverse reactions" to include, but not be limited to, many specific types of harm that are highly relevant to the ultimate question presented in a risk evaluation: "whether a chemical substance presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(b)(4)(A). Firms must maintain these records for 30 or 5 years, depending on the circumstances. 40 C.F.R. § 717.15(d).

EPA should use its authority to request these records on alleged significant adverse reactions caused by the ten chemicals analyzed in the scope documents and add them to the administrative record for the relevant chemical. EPA can request records from manufacturers and processors that reported the chemicals in response to any § 8(a) and 8(d) rules or in response to CDR reporting. *Id.* § 717.17. EPA can request those records by letter. *Id.* § 717.17(b). Finally, EPA can also notify all people holding such records to provide them by a notice in the Federal Register. *Id.* These records may provide valuable information on hazards, exposures, and conditions of use, since the records may reveal not only significant adverse reactions but also information about the specific exposure and use that may have caused the reaction.

B. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps.

EPA should make robust use of its § 4 authority to fill any gaps in information. EDF recognizes that time constraints apply to these first ten chemicals and thus some types of testing may not be possible, but going forward, EPA needs to use its authority fully and do so in a timeframe that ensures it will have all of the information it needs to conduct risk evaluations.

As EPA moves forward on the first 10 risk evaluations, it should first clearly identify *all* significant information gaps on hazards or exposures. Based on its own regulation, EPA must then use its authority under TSCA § 4(a)(2) to require the development of new information to fill those gaps wherever possible. Information that EPA can generate under TSCA § 4(a)(2) is reasonably available under EPA's own regulation as "information that EPA *** can reasonably generate [and] obtain *** for use in risk evaluations." 40 C.F.R. § 702.33. Thus, EPA should identify such information gaps and then promptly require the conduct of all testing that can be done and still meet the statutory deadlines for the risk evaluations.

TSCA § 4(a)(2) provides that EPA "may, by rule, order, or consent agreement require the development of new information relating to a chemical substance *** if the Administrator determines that the information is necessary *** to perform a risk evaluation under section 6(b)." 15 U.S.C. § 2603(a)(2)(A)(i). Congress provided this additional testing authority allowing EPA to require testing or other data development efforts solely upon a determination "that the information is necessary *** to perform a risk evaluation under section 6(b)." *Id.* In light of deadlines, EPA can and should use its order authority and does not need to make the additional findings required for a rule under TSCA § 4(a)(1).

In places in these scopes, EPA seems to be going out of its way to avoid using its information authorities. For example, in numerous places in these scopes, with respect to exposure, EPA indicates that "[f]or conditions of use where data are limited or not available, [it will] review existing exposure models that may be applicable in estimating exposure levels" (p.43). This language suggests that EPA will simply default to models rather than use its authority to get needed information. In EDF's view, EPA should first use its authorities under TSCA §§ 8 and 4 to fill those information gaps, rather than rely on models to compensate for lack of information. This is not to say that exposure models do not have a role, but they are not a basis for avoiding the obligation to collect information.

Our review of the scopes indicates that there are significant gaps in the information. Where possible EPA needs to fill those gaps. When it is not possible, consistent with TSCA § 26, EPA needs to identify those gaps and characterize the uncertainty in the draft risk evaluations. To cite just one example, in the scope for Methylene Chloride EPA completely fails to mention an information gap earlier identified in the Work Plan. Specifically, the 2014 Work Plan Assessment for Methylene Chloride identified both developmental neurotoxicity and immunotoxicity from chronic exposure as important data gaps, impacting the selection of the point of departure:

> There is uncertainty about chronic exposure impacts on the nervous system function. The nervous system has been well studied and identified as very sensitive for acute effects. However, there is a paucity of data on chronic neurological impacts, especially developmental neurotoxicity. Likewise, there is limited information about immunotoxicity following chronic exposure to DCM. Existing hazard studies are not sufficient for dose response analysis to provide a lower point of departure than existing adverse findings in the liver from chronic exposures."

See Methylene Chloride: Paint Stripping Use, TSCA Work Plan Chemical Risk Assessment at p.115, https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf

C. If EPA already has relevant information, it is reasonably available and EPA should consider it.

The strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." *See, e.g.*, Asbestos literature at p.13. But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation *** is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available, EPA must review it.

In addition, much of this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. First, historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act. Second, the Lautenberg Act greatly increased the requirements companies must meet to assert CBI claims. For example, information only qualifies for protection if the submitter asserts *and* substantiates that it has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c). Thus, even if the information once merited protection, it may no longer be confidential under the standards of TSCA § 14. Third, as a general rule, TSCA § 14(b)(2) provides that health and safety studies and information from health and safety studies are not entitled to confidential treatment, so much of this information may not be confidential under that provision.

To fulfill its duties under TSCA, EPA must review this reasonably available information and identify that which is potentially relevant to the risk evaluations. Where information is relevant, EPA should also consider whether the information meets the strict requirements for nondisclosure under TSCA § 14. If not, EPA should add it to the administrative record for review by the public. Whether or not it meets those requirements, EPA should then determine whether and how to consider the information in evaluating these chemicals. Notably, TSCA § 26(j) requires that, "subject to section 14," EPA "shall make

available to the public *** a list of the studies considered by [EPA] in carrying out each such risk evaluation, along with the results of those studies." 15 U.S.C. § 2625(j).

D. When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information.

In the literature searches, EPA sometimes states that it relied on recent assessments, and then only performed research for dates beyond those assessments. *See, e.g.*, 1,4-Dioxane, Strategy for Conducting Literature Searches for 1,4-Dioxane: Supp. File for the TSCA Scope at p.7, 9-10, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0047. EPA needs to provide a short analysis presenting its review of the prior analysis to ensure it adequately captured and addressed all reasonably available information as of the date of its publication, particularly given the expanded obligations under the Lautenberg Act. If EPA finds it was not adequate, then EPA should broaden its literature search.

III. EPA needs to take additional steps to ensure both the completeness and accuracy of the information it relies upon.

As explained above, EPA should rely on its authorities under TSCA §§ 8 and 4 to obtain all reasonably available information. Those authorities include a number of measures to ensure the accuracy and completeness of the data relied upon. To the extent EPA relies on voluntarily submitted information, EPA needs to take additional steps to ensure the accuracy and completeness of the information. Otherwise, EPA will violate TSCA § 26 by failing to make decisions "in a manner consistent with the best available science." 15 U.S.C. § 2625(h)

A. EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals.

EPA has requested in each of the scopes that industry and other stakeholders provide information. While this voluntary request was a reasonable first step towards obtaining the necessary information, EPA has failed to provide any account for how this voluntary approach to collecting information will result in EPA obtaining all "reasonably available" information as EPA has defined that term. There are several obvious problems and limitations with this voluntary approach which EPA has not even acknowledged, much less addressed.

First, a voluntary call is much less likely to produce all of the necessary information than rules mandating that affected parties provide the requested information. If manufacturers and processors are legally required to provide the information, that legal obligation provides a strong incentive for them to collect and submit all relevant information. Absent that incentive, some companies may choose to focus time and attention on other matters. Indeed, the burdens (whether one considers them heavy or light) of collecting and submitting information counsel in favor of issuing mandatory rules. *If* the process of

collecting and submitting the information is not onerous or difficult, then using rules to require the submission of the information will do little if any harm to the regulated industry, and use of rules will ensure EPA has a complete picture and increase credibility. Alternatively, to the extent that the process is onerous or difficult, it is even more important that EPA *require* the submission of the information, because otherwise those burdens will likely discourage stakeholders with relevant information from collecting and submitting the information.

Second, EPA has provided no empirical evidence establishing that this voluntary approach will result in EPA obtaining all "reasonably available" information. Unless EPA has some empirical basis for stating that the voluntary approach will allow EPA to obtain all reasonably available information that it can obtain under its legal authorities, EPA must rely on its existing authorities to obtain a complete set of information.

Indeed, EPA's prior experience with voluntary reporting provides strong evidence that a voluntary approach is unlikely to provide complete and accurate data. For example, an EPA advisory committee called for the development of nanomaterial reporting rules in 2005, but EPA instead spent several years developing and carrying out a voluntary reporting program, the Nanoscale Materials Stewardship Program (NMSP). This voluntary reporting program produced minimal information as revealed by EPA's 2009 interim report on the NMSP. Nanoscale Materials Stewardship Program, Interim Report, OPPT (Jan. 2009), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0003. "[I]n the report EPA estimated that companies provided information on only about 10 percent of the chemical substances manufactured at the nanoscale that may be commercially available in 2009." 80 Fed. Reg. 18,330, 18,334 (April 6, 2015). In 2017, over a decade after the data need was identified, EPA finally finalized a § 8(a) reporting rule to acquire the data. 82 Fed. Reg. 3641 (Jan. 12, 2017). Given the past failures of voluntary approaches, EPA should not rely on them here.

Third, manufacturers and processors of these chemicals have a vested interest in EPA finding that the chemicals do not present an unreasonable risk. A no-unreasonable-risk finding reduces the likelihood of government regulation, including potential restrictions on risky chemicals, and it may reduce any stigma they may otherwise face in the marketplace. The financial costs of regulation may ultimately be very high for some specific firms and individuals, and even if not, many firms and individuals may *believe* that the costs of regulation will be high. These companies have a "financial interest" in the outcome of these proceedings, and they are not impartial. *See, e.g.*, 28 U.S.C. § 455(b)(4) (requiring Judges to disqualify themselves in proceedings where they have a financial interest). Because of this reality and appearance of partiality, relying solely on voluntary measures decreases the credibility of these risk evaluations.

Relying solely on voluntary presentation of information raises the concern that the companies or trade associations may present an incomplete or skewed picture. Companies and trade associations may choose to "cherry pick" information and provide only the information that paints their chemicals in favorable light. They may provide only summaries of information that reflect conscious and subconscious judgment calls that result in unduly favorable conclusions; and without access to the full information neither EPA nor the public can independently assess such conclusions. They may choose

not to review records robustly when the review may disclose unfavorable information. They may seek to put their best foot forward and describe the ideal scenario of use and safety measures. Or, if they have unfavorable information, they may choose not to provide any information at all and simply not participate in these proceedings.

To be sure, members of the regulated community are crucial sources of information about their chemicals' uses, hazards, and exposures, but EPA cannot simply assume that they will voluntarily disclose unfavorable or complete information about their practices and products. *See* THE FEDERALIST NO. 51 (James Madison) ("If men were angels, no government would be necessary. *** [E]xperience has taught mankind the necessity of auxiliary precautions."); *Williams v. Pennsylvania*, 136 S. Ct. 1899, 1905-06 (2016) ("Bias is easy to attribute to others and difficult to discern in oneself. *** This objective risk of bias is reflected in the due process maxim that 'no man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome.'"). Here, manufacturers and processors obviously have an interest in the outcome, and EPA must craft its procedures and approaches with that reality in mind. Requiring the submission of information is the safest approach to ensuring that these parties provide all relevant information, and that is in turn crucial to establishing and demonstrating the credibility of this process.

If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information. First, EPA can require that certain information and underlying information be provided in full, which ensures completeness. In addition, a § 8(d) rule requires that people engage in an adequate search of records. 40 C.F.R. § 716.25. Second, submitters must file certification statements by authorized officials that certify that the submitted information has been submitted in compliance with the requirements of this process. *See, e.g.*, 40 C.F.R. § 711.15(b)(1). Third, submitters often must retain records of required submissions for a period of five years, and the retention of records can help encourage accurate reporting since those records would be available should a submission latter be investigated. *See, e.g.*, 40 C.F.R. § 711.25. None of these features apply to the voluntary requests for information EPA has indicated it is relying on.

In addition, as EDF has explained in prior comments, there are numerous reasons that it is important that the public have access to full studies and the underlying information, not simply robust or other study summaries. *See, e.g.*, EDF Comments on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act, Comment at p.37, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074. Without access to full studies, the public will be challenged or unable to assess and comment on the quality of the studies used by the agency. *Id.* EDF reincorporates and reiterates the numerous points made in support of public access to the full studies here. *Id.* These points also support the importance of EPA obtaining the full studies.

B. For voluntary submissions, EPA should take additional steps to ensure completeness and accuracy and to vet information based on underlying data.

To the extent it relies on voluntary submissions, EPA can and should take additional steps to better ensure that the voluntary information it receives is accurate and complete. EPA would need to develop a far more rigorous and structured process than it currently has. For example, EPA's submission process does not appear to require anyone to certify that the information in their comments is accurate or complete to the best of their knowledge. EPA should consider approaches for vetting statements and assertions, particularly when made by entities with a financial interest in the outcome of these risk evaluations.

EPA should also request that submitters always provide full studies, as well as underlying data whenever reasonably available or obtainable. Setting aside concerns about partiality, EPA needs the underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular submission.

In addition, EPA should seek input directly from workers for manufacturers and processors, providing them an easy method to submit information on workplace practices and conditions independently from management. EPA needs to take steps to allow workers to provide input in a manner that reduces the risks of any potential retaliation from management.

To give a few specific examples from the scopes:

In the Perchloroethylene scope (also known as tetrachloroethylene or PCE), EPA cites the Vinyl Institute's comments for the fact it can be a residual or byproduct in the manufacture of other chemicals. *See* Perchloroethylene, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0732 (citing comment at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0013). That comment, in turn, contains a table claiming to summarize the approximate concentrations of Perchloroethylene in light and heavy end liquid intermediate streams yielded in the EDC/VCM process for manufacturing each of four chlorinated organic substances. The comment states that there is no residual Perchloroethylene in light liquid ends and 1.1% by typical weight in heavy liquid ends. But the comment does not provide or cite any underlying data supporting these findings. When commenters provide summary statements along these lines, EPA should give them little weight unless it also receives the underlying data to ensure that the reported results or conclusions drawn accurately reflect real-world conditions and to assess the level of certainty and scope of applicability that EPA can attribute to the results or conclusions. This point holds for all of the percentages set forth in that table, including those for the other three products.

Similar concerns arise for many of the other scopes. For example, in the Carbon Tetrachloride scope, EPA states that: "there are public comments, EPA-HQ-OPPT-2016-0733-0005 [3M] and EPA-HQ-OPPT-2016-0733-0017 [ACC], stating that carbon tetrachloride may be present in a limited number of industrial products with chlorinated ingredients at a concentration of less than 0.003% by weight." Carbon Tetrachloride, Scope at p.20, Docket ID: EPA-HQ-OPPT-2016-0733. But upon examining those

comments, they do not provide any of the underlying data or enough information to assess accuracy of the statement or the level of uncertainty that should apply to the results. The ACC comment is particularly difficult to assess. It involves multiple levels of hearsay, with ACC reporting statements that companies reported to it. Some of those companies acknowledge they are also relying on hearsay from suppliers and have not taken steps to confirm these concentrations. Those suppliers might also be relying on hearsay; it is simply not clear what the bases are for some of these values. Hearsay is, of course, particularly problematic when the statement serves the interest of the person submitting the evidence. *See, e.g.*, FED. R. EVID. P. 804(b)(5) (exception for statements against interest). As such, these concentrations arguably provide at best a "lower bound" estimate; they are not sufficient in terms of establishing that the actual concentrations are not higher. While no formal hearsay rule applies to these administrative proceedings and the hearsay evidentiary rule generally has limited applicability to technical studies and business records, it is relevant to the weight EPA should give these reported values given these circumstances. ACC does not disclose the companies providing the information, making it impossible for EPA to independently address these kinds of concerns. In addition, ACC's comment often fails to provide any clarity or detail as to how the concentrations were measured or assessed, much less provide the data underlying these claimed concentrations. The ACC comment asserts concentrations for 1,4-Dioxane, Pigment Violet 29, N-Methylpyrrolidone (NMP), Methylene Chloride (DCM), Carbon Tetrachloride, and HBCD, but for most of these concentrations, it is impossible for EPA or the public to assess whether they are accurate. For some of these concentrations, the comment states that Safety Data Sheets and Technical Data Sheets are provided with the comments, but EDF did not find any attachments with the comment containing those materials. In sum, EPA needs to scrutinize these voluntary submissions carefully and ensure access to the underlying information, which is necessary to assess the accuracy of the statements therein.

In the asbestos scoping document, EPA acknowledged that the analysis of the Chlor-Alkali industry was "primarily based on information provided by either the chlor-alkali industry or [the American Chemistry Council] and is meant to represent typical practices." *See* Asbestos, Scope at p.54, Docket ID: EPA-HQ-OPPT-2016-0736. EPA correctly recognized that EPA should "further evaluate how representative the processes witnessed at these two facilities are of processes at other plants." *Id.* at 23. EPA should take measures to ensure that its process will in fact accurately assess the full range of existing practices, relying on independent data where possible. Where independent data are unavailable, EPA should reach out to workers directly to better determine actual practices. Even when companies have good practices on paper, those practices may not be the reality on the ground.

EPA also needs to carefully scrutinize statements to ensure it correctly interprets them.

IV. These scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations.

Broadly viewed, the scopes do not meet several of the statutory requirements of TSCA. TSCA § 6(b)(4)(D) requires that EPA "shall, not later than 6 months after the initiation of a risk evaluation,

publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D). These scopes do not fully satisfy these requirements. Some aspects are plainly illegal under *any* interpretation of the statute, for the reasons given above, such as the statement that "EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11).[1] But many other aspects, while problematic, can be resolved by EPA in the next step: its development of problem formulations.

It is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. EDF believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified. With respect to susceptible populations, EPA should consider workers and, in most cases, pregnant women and children, to be potentially exposed or susceptible subpopulations. We identify below a number of specific examples where EPA's scopes are unclear and merit further study.

A. 1,4-Dioxane

EPA states: "EPA evaluated the weight of the evidence for cancer in humans and animals and concluded that 1,4-dioxane is 'likely to be carcinogenic to humans' based on evidence of carcinogenicity in several 2-year bioassays." 1,4-Dioxane, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0723. However, certain language in this section suggests that EPA may not include cancer as a hazard endpoint in the risk evaluation.

Indeed, EPA almost seems to suggest that inconclusive evidence regarding the "mode of action by which 1,4-dioxane produces liver, nasal, peritoneal (mesotheliomas) and mammary gland tumors" might form a basis for disregarding the evidence of such hazards. *Id.* at 35. As a general matter, EPA should not exclude observed hazards simply because the underlying MOA is not fully delineated or understood, doing so would significantly and inappropriately jeopardize the robustness and health-protections of the risk evaluation. If there is evidence of hazard, EPA should include it in the risk evaluation, even if the precise mode of action is not yet understood.

[1] As explained above, EPA puts too much weight on a floor statement from a single Senator, David Vitter. But even Senator Vitter stated that EPA must consider all conditions of use identified in the scope. *See* 114 Cong. Rec. S3520 (daily ed. June 7, 2016) (statement of Sen. Vitter). Despite that statement, the scoping documents all state that "during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11). Thus, EPA is inconsistent in how much weight it gives to Senator Vitter's statements, and EPA's current interpretation appears to contradict the views expressed throughout the legislative history by every single legislator. If EPA excluded uses identified in the scope, such as uses in the chlor-alkali industry (e.g., pp.20, 23-24), then EPA will be acting contrary to Senator Vitter's statement.

B. Perchloroethylene

The scope for Perchloroethylene states that "EPA expects to consider hazards identified in the recent assessment by the EPA Integrated Risk Information System (IRIS) Program: neurotoxicity, kidney toxicity, liver toxicity, developmental and reproductive toxicity and cancer. Support for an association with immune and blood effects was less well characterized." Perchloroethylene, Scope at p.11, Docket ID: EPA-HQ-OPPT-2016-0732. It is unclear from the scope whether EPA intends to include immune and blood effects in particular.

C. Trichloroethylene (TCE)

In the scope for TCE, EPA suggests that TCE's use as a spot remover will not be analyzed because it was previously analyzed in a risk evaluation. TCE, Scope at p.25, Docket ID: EPA-HQ-OPPT-2016-0737. That approach may be reasonable if EPA finalizes its proposed ban on this use of TCE to address those risks, as discussed more below. But that approach only applies to those spot remover uses that have previously been analyzed, specifically commercial dry cleaning facilities. This risk evaluation needs to consider TCE's use as a consumer spot remover. Those uses have not been analyzed in-depth, and the 2014 work plan assessment recognized that some such products may contain TCE as a main ingredient. *See* Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses, TSCA Work Plan Chemical Risk Assessment at p.52, https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

D. N-Methylpyrrolidone (NMP)

The NMP scope has numerous inconsistencies with respect to its identification of the endpoints to be assessed. EPA begins by acknowledging that a "number of human health hazards have been identified for NMP including adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems." N-Methylpyrrolidone, Scope at p.36, Docket ID: EPA-HQ-OPPT-2016-0743. EPA also states that: "EPA expects to consider all potential hazards associated with NMP." *Id.* EDF completely agrees with that approach. However, the description under section 2.42 Human Health Hazards indicates that EPA intends to focus on a narrower set of hazards (acute toxicity and reproductive/developmental toxicity), and provides no justification or even explanation for excluding some of the hazards that it previously identified.

E. Potentially exposed or susceptible subpopulations

EPA also does not identify pregnant women, women of childbearing age, or the developing fetus as potential exposed or susceptible subpopulations for either N-Methylpyrrolidone (NMP) [NMP, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0743] or TCE [TCE, Scope at pp.37-38, Docket ID: EPA-HQ-OPPT-2016-0737], despite the fact that EPA's previous risk assessments on these two chemicals identify women of childbearing age and the developing fetus as a primary susceptible population (in addition to workers). EPA's failure to identify these populations in the scopes is both contrary to law and an abuse of discretion. TSCA § 3(12) defines "potentially exposed or susceptible subpopulation" to include "a

group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance *** , such as infants, children [or] pregnant women." 15 US.C. § 2602(12). Here, EPA has previously found that "women of childbearing age" are at greater risk of adverse health effects from these chemicals. 82 Fed. Reg. 7432, 7434 (Jan. 19, 2017); 82 Fed. Reg. 7464, 7467 (Jan. 19, 2017).

Furthermore, TSCA requires that EPA identify "the potentially exposed or susceptible subpopulations the Administrator expects to consider" in the scopes. 15 US.C. § 2605(b)(4)(D). While EPA has considered those at greater risk due to *increased exposure* in the scopes to some extent, the agency appears to defer the process of identifying populations with *greater susceptibility* to the problem formulation or risk evaluation stage: "In developing the hazard assessment, EPA will also evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s)." *See, e.g.*, NMP, Scope at pp.36-37, Docket ID: EPA-HQ-OPPT-2016-0743; 1,4-Dioxane, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0723.

V. EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures.

The scoping documents generally acknowledge the need to analyze activities related to a chemical's distribution, but EPA will need to analyze these exposures more robustly than the scopes currently reflect. *See, e.g.*, 1,4-Dioxane, Scope at p.22, Docket ID: Docket ID: EPA-HQ-OPPT-2016-0723.

The scoping documents give little, if any, attention to potential releases and exposures resulting from accidental releases. EDF does not suggest that EPA needs to consider every possible scenario, but the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks. For example, as and after Hurricane Harvey passed through Houston, over 40 sites released toxic chemicals into the environment. *See, e.g.*, More Than 40 Sites Released Hazardous Pollutants Because of Hurricane Harvey, https://www.nytimes.com/interactive/2017/09/08/us/houston-hurricane-harvey-harzardous-chemicals.html?_r=0. Given the *known* accidental releases, the huge number of petrochemical plants and refineries in the Houston area, and the likelihood that flooding there may become more common in light of climate change, such events are clearly reasonably foreseen and hence EPA needs to give more consideration to the potential for accidental releases.

VI. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures.

Language used in the scopes suggests that EPA may inaccurately assume that people comply with all warning labels and always use personal protective equipment (PPE). EDF strongly urges EPA to consider real-world exposures reflecting the reality of the sometimes low-compliance with or non-existence of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by

either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). And absent empirical evidence establishing the extent to which people are using these measures, EPA should assume that they may not be. Indeed, EPA's need for accurate information about actual compliance is another reason to rely on its authorities under TSCA § 8 to mandate that manufacturers and processors provide that information. In addition, it bears noting that reliance on PPE as a primary measure to protect workers is counter to OSHA's Industrial Hygiene Hierarchy of Controls (HOC), a long-standing principle that prioritizes measures to eliminate or reduce the presence of a hazard in occupational settings (e.g., substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves, such as through reliance on PPE and warning labels. The HOC exemplifies the best available science for creating safe, healthful workplace environments.

As an example of a problematic reference to PPE in the scopes, in the asbestos scope, EPA stated that "[d]ermal exposure is unlikely due to glove use in the workplace." Asbestos, Scope at p.37, Docket ID: EPA-HQ-OPPT-2016-0736. But EPA cites no evidence supporting this assumption. While gloves may be used in many workplaces, EPA needs to provide evidence of the extent of such use. Among other things, EPA correctly noted earlier that "certain conditions of use, such as a mechanic changing asbestos-containing brakes, may also result in dermal exposure." *Id.* at 35. Is there any evidence that all or even most mechanics wear gloves when changing brakes? Indeed, EPA should identify mechanics as a relevant potentially exposed or susceptible subpopulation based on their exposure to brakes.

In comments EDF has submitted in these dockets, EDF previously commented on the serious limitations of labeling and PPE, as well as the importance of adherence to the hierarchy of controls to limit workplace exposures. *See, e.g.*, EDF comments at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0046, March 15, 2017; and at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052, November 21, 2016. EDF reincorporates and reiterates the points made in those comments here.

VII. EPA's decision not to examine uses addressed by its planned § 6(a) rules governing certain uses of TCE, DCM, and NMP is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses.

For Trichloroethylene (TCE), Methylene Chloride (DCM), and N-Methylpyrrolidone (NMP), EPA states that conditions of use previously examined will not be re-evaluated. TCE, Scope at p.9, Docket ID: EPA-HQ-OPPT-2016-0737; DCM, Scope at p.29, Docket ID: EPA-HQ-OPPT-2016-0742 ("This includes uses assessed in the U.S. EPA (2014a) risk assessment and therefore those uses are out of scope for the risk evaluation."); NMP, Scope at pp.20, 28, Docket ID: EPA-HQ-OPPT-2016-0743 ("This includes uses assessed in the previous EPA risk assessment (U.S. EPA, 2015) and therefore those uses are out of scope for the risk evaluation."). EPA has previously found these uses even by themselves present unreasonable risks to human health. In addition, these uses have the potential to increase the total

exposure of people to these chemicals. As a result, EPA can only reasonably exclude these uses if it finalizes the proposed rules to ban these uses. EDF strongly supports those bans for the reasons it articulated in its prior comments.

If EPA does not finalize these bans, then excluding these uses is both contrary to law and arbitrary and capricious. By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses *unless* EPA has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals.

* * * * *

EDF appreciates the opportunity to provide comments and EPA's consideration of them.

Environmental Defense Fund Comments on

Ten Scopes under the Toxic Substances Control Act

Docket IDs: EPA-HQ-OPPT-2016-0725 (Pigment Violet 29), EPA-HQ-OPPT-2016-0723 (1-4, Dioxane), EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene), EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride), EPA-HQ-OPPT-2016-0735 (HBCD), EPA-HQ-OPPT-2016-0736 (Asbestos), EPA-HQ-OPPT-2016-0737 (Trichloroethylene), EPA-HQ-OPPT-2016-0741 (1-Bromopropane), EPA-HQ-OPPT-2016-0742 (Methylene Chloride), and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone)

Submitted Tuesday September 19, 2017

The Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the scopes for the risk evaluations for the first ten chemicals being evaluated under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

In addition to specific comments on each chemical, EDF is providing broad comments addressing the scopes of risk evaluations for the first 10 chemicals as well as others in the future. While our comments are broadly applicable to all of the scope documents, we include examples from specific scopes to illustrate flaws and limitations.

As explained below, these scopes deviate from certain requirements of the law and in places are too unclear and vague or ambiguous to allow us to provide definitive comments. EDF recognizes that EPA was working under tight deadlines in producing these scopes – a problem it further exacerbated by EPA's decision to make major, late changes to the risk evaluation rule. EPA should take advantage of the upcoming problem formulation stage to address the many problems we identify below, and to more clearly and transparently explain its plans for these risk evaluations.

Before discussing the merits of the scoping documents, EDF provides the following clarification about its citation approach. Each scoping document contains largely identical, boilerplate language providing the agency's overall legal approach to "conditions of use" as well as its approaches on some other issues. Indeed, each document includes the same typos or misquotes of the underlying law. For ease of reference and to reduce excessive citations, EDF quotes from the asbestos scoping document and provides simply the page number when addressing these broader legal problems that are present in each scoping document. These comments equally apply to all scoping documents since they all contain

this same language; the only difference is page number. When EDF is specifically quoting another scoping document, we provide a citation clarifying that point.

Contents:

I. TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use.

EPA's scoping documents (pp.11-13) state that EPA has determined that "certain activities may not generally be considered to be conditions of use" (p.11) and also that EPA may "exclude certain activities that EPA has determined to be conditions of use" (p.12). EPA's approach asserts that EPA is allowed to ignore numerous circumstances falling within the statutory definition of "conditions of use" and is contrary to law. For the current set of chemicals under review, EPA may well be ignoring circumstances leading to ongoing exposures, and as a result, will fail to evaluate the risks the chemicals actually pose to human health and the environment.

TSCA's language and structure unambiguously foreclose EPA's interpretation. EPA's decision to disregard certain uses and exposures is also "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to consider "factors which Congress has not intended it to consider [and] entirely fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, as the scoping documents themselves reveal, this approach leads to irrational and arbitrary applications. Instead, EPA should be guided by the statutory language and consider all of those circumstances falling within the definition of "conditions of use." EPA should evaluate all of the circumstances revealed by the evidence of use and exposure, not ignore evidence because of self-imposed blinders.

A. The plain text, overall structure, purpose, and legislative history of TSCA indicate that EPA has to determine whether a chemical substance presents an unreasonable risk comprehensively, under all of its conditions of use.

i) *The plain text requires EPA to consider all conditions of use.*

Statutory interpretation should begin, as always, with the language of the statute. The plain language of both the risk evaluation provision and the definition of conditions of use support the interpretation that EPA must consider all circumstances falling within the statutory definition of "conditions of use." The main risk evaluation provision, TSCA § 6(b)(4)(A), directs that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). Inserting the statutory definition of conditions of use, this provision provides that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* §§ 2605(b)(4)(A), 2602(4). Thus, EPA has to analyze the risks of a substance under the circumstances described in the definition of "conditions of use," and no qualifying language allows EPA to exclude circumstances within that definition. The clause "as determined by the Administrator" calls for a factual finding or determination to be made by EPA. The relevant dictionary definition of "determine" is to "ascertain or establish exactly, typically as a result of research or calculation." OXFORD

AMERICAN DICTIONARY 474 (3d ed. 2010). While EPA may exercise reasonable judgment when interpreting "reasonably foreseen," nothing in this language grants EPA discretion to *ignore* factual circumstances that fall within the definition of "conditions of use." Indeed, statutes often direct agencies "to determine" things or make "determinations," and it is understood that the agency must make the finding required by the statutory language.

EPA's position that it can ignore known and foreseeable uses violates the text of the law. In the scoping documents, EPA asserts that it may ignore "legacy uses" and "associated disposals," impurities, alleged "de minimis" exposures, intermediates, conditions of use within closed systems, and conditions of use that have been analyzed by another regulatory agency (p.12). But "conditions of use" expressly includes "the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen to be to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). And every one of those circumstances is a "known" or "reasonably foreseen" "manufacture", "process[ing]," "use," or "disposal of" a chemical substance. Congress expressly chose to define "conditions of use" broadly to include not only "intended," but also "known" or "reasonably foreseen" manufacture, processing, distribution, use, and disposal. 15 U.S.C. § 2602(4). Disregarding chemical substances present as impurities or byproducts in the scoping documents, for example, because they are not "intended" essentially reads the other two scenarios out of the statute. Similarly, all the other identified conditions of use are also "intended, known, or reasonably foreseen." For example, EPA's scope suggests that 90% of the domestic production of Pigment Violet 29 "is processed as a site-limited intermediate." Pigment Violet 29, Scope at p.19, Docket ID: EPA-HQ-OPPT-2016-0725. It would absurd to ignore these intermediate uses when analyzing this chemical; doing so will lead to a truncated and incomplete analysis. Similarly the decision to exclude 1,4-dioxane's presence in numerous consumer, commercial, and industrial products as a byproduct of ethoxylation is entirely inappropriate, and will result in deficient and erroneous evaluation and determination of the chemical substance's risks. The same points can be made for many of the other chemicals used as intermediates or present as byproducts of chemical or product manufacture.

In contrast to the correct interpretation, EPA's new interpretation finds no support in the text. In the final risk evaluation rule (82 Fed. Reg. 33,726, 33,729 (July 20, 2017)), the only statutory textual basis for EPA's theory appears to be the "expects to consider" clause in the scope provision, TSCA § 6(b)(4)(D), requiring EPA to "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator *expects to consider*." 15 U.S.C. § 2605(b)(4)(D). But "expects to consider" does not mean "chooses to consider" or "prefers to consider." It is not the language of discretion; it is temporal language of anticipation or prediction. The dictionary definition of "to expect" is to "regard (something) as likely to happen." OXFORD AMERICAN DICTIONARY 609 (3d ed. 2010). This language indicates that, in the scope, EPA should describe what it anticipates studying, but it does not state that EPA has discretion to choose to ignore intended, known, or reasonably foreseen uses, hazards, or exposures. Moreover, the provision dictating what EPA must consider during a risk evaluation does not limit EPA's analysis to conditions of use identified in the scope. 15 U.S.C. § 2605(b)(4)(F). Indeed, EPA must consider all such conditions to fulfill its requirement that EPA account for the "likely duration, intensity, frequency, and

number of exposures under the conditions, where relevant." 15 U.S.C. 2605(b)(4)(F)(iv). Thus, the statutory language does not support EPA's assertion of discretion, including EPA's decision to limit its analyses to those factors identified in each scope. For example, under the rule of the last antecedent, the phrase "the Administrator expects to consider" does not even *modify* "conditions of use" or "hazards" or "exposures." Notably, EPA has so little regard for the statutory language that it repeatedly misquotes this language in significant ways.

Textually, EPA's argument also directly conflicts with TSCA § 26(k). 15 U.S.C. § 2625(k). TSCA § 26(k) requires EPA to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." *Id.* Notably, this requirement does not include *any* conditional phrase that modifies "conditions of use." And Congress included this provision to ensure that EPA could not ignore "reasonably available" "information relating to a chemical substance or mixture"; the purpose of this provision is to compel EPA to consider all reasonably available information. It would undermine this directive if EPA chooses to arbitrarily ignore certain uses and related exposures.

ii) *TSCA's overall structure requires EPA to consider all of the conditions of use.*

TSCA provisions direct EPA to prepare risk evaluations and the related findings for "chemical substances," *as a whole*, not for specific or limited conditions of use of those substances. For example, the risk management provision expressly requires EPA to address risks when the risks arise from combined exposure. TSCA § 6(a) provides that: "If [EPA] determines in accordance with [the risk evaluation provision] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, *or that any combination of such activities*, presents an unreasonable risk of injury to health or the environment," then EPA must issue a risk management rule. 15 U.S.C. § 2605(a); *see also* 15 U.S.C. § 2608(a) (using same language in provision governing requests to other federal agencies to address risks). Thus, if "any combination" of conditions of use presents an unreasonable risk, EPA must issue a risk management rule. But EPA must analyze *all* of these activities to assess whether *any combination* presents a risk.

When describing the end of a risk evaluation, TSCA requires EPA to make a finding about the "chemical substance" with no reference to conditions of use. *See, e.g.*, 15 U.S.C. § 2605(c)(1), (*i*) ("If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A)," then EPA must issue a regulation to address the unreasonable risk.). The absence of any reference to conditions of use makes it clear that EPA must make a finding for a chemical substance as a whole, not one limited to certain conditions of use. Notably, in the final prioritization rule, EPA correctly reasoned that this type of language indicated that EPA had to consider *all* uses in prioritization. *See* 82 Fed. Reg. 33,753, 33,755 (July 20, 2017) ("The statute directs EPA to make prioritization determinations on a 'chemical substance' or 'substance,' not on 'uses,' *see, e.g.*, 15 U.S.C. §§ 2605(b)(1)(A)-(C), and in most cases, without reference to 'the conditions of use.'"). This reasoning equally applies to risk evaluations.

iii) *TSCA's purpose, as well as basic logical reasoning and the best available science, require EPA to consider all conditions of use to assess a chemical substance as a whole.*

The purpose of the risk evaluation is to analyze the risks of a substance based on an assessment of its hazards and exposures. Ignoring potential exposures at the outset undermines that purpose. And science and logic do not support EPA's exceptions. For example, EPA states that it may disregard so-called "de minimis" exposures from conditions of use that occur in a closed system or use as an intermediate (p.12). But intermediates are often not completely consumed in chemical reactions and may remain as a residual in final reaction products. *See, e.g.*, California Department of Toxic Substances Control, Spray Polyurethane Foam Systems Containing Unreacted Methylene Diphenyl Diisocyanates, http://www.dtsc.ca.gov/SCP/Spray_Polyurethane_Foam.cfm (last visited Sept. 18, 2017). So the presumption that intermediates lead to a "de minimis" exposure is often contrary to the scientific evidence. In addition, intermediates must still be manufactured as well as typically being stored, transferred, or distributed, all of which are activities that can lead to exposures – including to workers, whom TSCA expressly identifies as a "potential exposed or susceptible subpopulation." Similarly, unintended impurities or contaminants can nonetheless lead to exposures and hence risks to human health or the environment, the significance of which needs to be determined in conducting a risk evaluation. *See infra* at pp.10-11 (discussing 1,4-dioxane). Ignoring them at the outset is contrary to the purpose of TSCA and risk evaluations, as well as the law's requirement that EPA rely on the best available science.

To be sure, EDF generally agrees with EPA's statement that "all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk." 82 Fed. Reg. at 33,734. Legally, EPA may be able to provide a concise and scientifically valid finding that a particular condition of use—such as the use phase of a chemical used as an intermediate—leads to little or no exposure and risk in a particular case, based on less than an in-depth analysis. And TSCA does not require a quantitative evaluation when a qualitative evaluation is determined and documented to be appropriate. But TSCA does not authorize EPA to simply "exclude" conditions of use at the outset as a matter of legal discretion. Furthermore, EPA must provide a scientific, data-backed rationale for why it decides a less extensive evaluation is sufficient, and cannot merely rely on a lack of data for such a decision.

EPA is imposing blinders on its analysis by asserting its authority to refuse to look at certain conditions of use, including known uses and disposals, and the result is that EPA is overlooking exposures in the real world. This approach is both contrary to law and arbitrary and capricious, as explained *infra* at Part I.D.

iv) *The legislative history does not justify or even lend support to EPA's approach.*

To justify its new position, EPA has emphasized the "legislative history" (p.11). But the legislative history, read as a whole, does not support EPA's approach. In the risk evaluation rule, EPA claims that the "legislative history of the amended TSCA *** explicitly states that the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation." 40 Fed. Reg. at 33,728 (citing 114 Cong. Rec. S3519-20 (daily ed. June 7, 2016) (statement of Sen. Vitter)). EPA relies on a floor

statement from a single Senator, which is one of the least illuminating forms of legislative history. EPA ignores that the rest of the legislative history reveals that other Senators thought that the statutory language would require EPA to consider all conditions of use in risk evaluations under the Lautenberg Act. Four principal Democratic negotiators of the legislation submitted a statement to the record that: "[t]he definition of 'conditions of use' described above plainly covers all uses of a chemical substance." 114 Cong. Rec. S3516 (daily ed. June 7, 2016). Similarly, when explaining why the bill expressly "grandfathered" in prior risk assessments (such as for Methylene Chloride), these negotiators explained that the provision was necessary because those "risk assessments for these chemicals were not conducted across all conditions of use." *Id.* at S3519. This explanation clearly reflects that *future* risk evaluations under TSCA would have to be conducted "across all conditions of use."

Unlike the text and structure of TSCA, the legislative history is somewhat ambiguous at points, although, if anything, it supports the position that EPA must consider "all conditions of use" since more Senators expressed that view and they did so in a formal statement.

B. Conditions of use expressly include certain so-called legacy uses and associated disposals.

In each of the scopes EPA stated that it *will* exclude so-called "legacy uses" and "associated disposal," (p.12) and EPA appears to rely on its reasoning from the risk evaluation rule. 82 Fed. Reg. at 33,729-30. EPA has asserted that no statutory text addresses this issue, and EPA stated that the use of the phrase "to be" in the definition of "conditions of use" implies a prospective application. 82 Fed. Reg. at 33,730; *see* 15 U.S.C. § 2602(4) (defining conditions of use to "mean[] the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen *to be* manufactured, processed, distributed in commerce, used, or disposed of") (emphasis added). EPA also (inaccurately) asserted that it did "not have an effective tool to address risks found to arise from uses in consumer settings if there" is no on-going manufacture, processing, or distribution. 82 Fed. Reg. at 33,730. But none of this reasoning survives scrutiny.

EPA's argument based on tense clearly does not apply to the legacy uses and associated disposals. If a chemical substance is present in a product or material that an industrial, commercial, or residential consumer is still using, then the substance is known "to be" used in that circumstance. Similarly, if a substance has not been disposed of yet, its disposal is in the future and reasonably foreseeable. As a result, these "legacy uses" and "associated disposal[s]" fall squarely within TSCA's definition of "conditions of use," which includes the "circumstances *** under which a chemical substance is *** known *** to be *** used, or disposed of." 15 U.S.C. § 2602(4). EPA has presented no textual basis for treating the first three participles in the list in this definition (manufactured, processed, and distributed in commerce) differently than the last two participles (used and disposed of).

EPA's theory that § 6 focuses on the "continuing flow of chemical substances" in "their lifecycles" (p.12) completely ignores that the use and disposal of a chemical is *part* of the lifecycle of a chemical, as defined by Congress in TSCA. Indeed, chemicals that are still in use are still "distributed in commerce" as that term is defined in TSCA. 15 U.S.C. § 2602(5). In the final risk evaluation rule, EPA stated that it

"believes the statute is better interpreted to focus on the prospective flow of the chemical substance," 80 Fed. Reg. at 33,730, but Congress expressly covered substances *after* their introduction into commerce as well.

EPA also justified its decision to ignore legacy uses by claiming it lacks tools to address risks from uses in consumer settings if there is no on-going commercial manufacture, processing, or distribution. 80 Fed. Reg. at 33,730. But TSCA § 6(a) expressly provides EPA with authorities that could manage some of these risks, even if it does not provide as broad authority as it does over manufacturers and processors. *See* 15 U.S.C. § 2605(a). For example, at risk management, EPA may impose "[a] requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture." *Id.* § 2605(a)(5). For example, EPA could ban the sale or future use of products containing a chemical even if that chemical is no longer in production in the United States, or EPA could require that such items be labeled. EPA may also impose "[a] requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or *by any other person* who uses, or disposes of, it for commercial purposes." *Id.* § 2605(a)(6)(A) (emphasis added).

In any event, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Indeed, in order to assess real-world risks of a chemical using the best available science, EPA needs to consider even those exposures over which it has limited or shared control. This approach is particularly appropriate given TSCA § 9's referral provisions.

C. The text and overall structure of TSCA makes it clear that EPA has to analyze uses, even if they have been assessed by another agency or are within another agency's jurisdiction.

EPA also stated that it may "exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risk" (p.12). But EPA provides no textual basis for ignoring those uses, which are often "circumstances *** under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Nothing in the risk evaluation provision or definition of conditions of use authorizes EPA to ignore conditions of use because of other agencies' jurisdiction over chemical substances. And several other provisions of TSCA indicate that Congress intended for EPA to consider such exposures, except to the extent Congress explicitly provided otherwise.

First, TSCA § 9(a) provides a detailed procedural mechanism for EPA under certain circumstances to request for another federal agency to address an unreasonable risk arising from a chemical substance that EPA has identified. 15 U.S.C. § 2608(a). This request then triggers a number of duties for both EPA and the other agency, requiring one of the two agencies to take action to address the risk. Thus Congress intended for EPA to prepare risk evaluations analyzing uses that might be addressed by another agency, and Congress created a substantive and procedural mechanism to resolve overlapping jurisdiction only *after* completing the risk evaluation. If EPA could just ignore risks arising from

conditions of use that fall within other agencies' jurisdiction, or if Congress meant for EPA to defer to those agencies' current regulatory approach to those chemicals at the outset before conducting a risk evaluation, then EPA might never make the finding that triggers the § 9(a) process. Here again, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Given that Congress expressly addressed the issue of overlapping regulatory jurisdictions in TSCA § 9, EPA cannot avoid those procedures by simply ignoring uses that fall within another agency's jurisdiction. Furthermore, EPA is expressly required to evaluate exposures from combinations of activities, which it cannot do if it excludes conditions of use at the outset that have been evaluated or regulated by another agency, particularly when that risk management is not an outright ban.

Second, Congress expressly exempted certain regulated chemicals or uses of chemicals from EPA's authority when it defined "chemical substance" in TSCA § 3(2). 15 U.S.C. § 2602(2)(B). For example, "chemical substance" does not include certain materials as defined in the Atomic Energy Act of 1954. *See id.* § 2602(2)(B)(ii), (iv). Thus, when Congress intended for EPA not to regulate certain conditions of use because they were regulated under other specific federal statutes, Congress expressly excluded those conditions of use. That Congress chose a limited, specific set of exclusions indicates that Congress did not intend for EPA generally to ignore other conditions of use even where they fall under other federal regulatory schemes.

D. The scopes contain incoherent and arbitrary and capricious reasoning because of EPA's approach to conditions of use.

EPA's illegal approach to "conditions of use" leads it to put "blinders" on regarding certain uses, exposures, and risks. The result is "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to have considered "factors which Congress has not intended it to consider [and] entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. It also violates several provisions of TSCA § 26 because by ignoring uses, exposures, and related information, EPA will not be acting "consistent with the best available science," EPA will not base decisions on "on the weight of the scientific evidence," and EPA will not "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h), (*i*), (k). In addition, because EPA's distinction is a false one untethered to the information, EPA seems to treat certain conditions of use inconsistently throughout the documents.

For example, in the 1,4-dioxane scope, EPA states that it will not consider risks arising from 1,4-dioxane when it is present as a by-product or residual contaminant from the manufacture of other chemicals. *See* 1,4-Dioxane, Scope at p.21, Docket ID: EPA-HQ-OPPT-2016-0723. But EPA identifies numerous products that "potentially contain[] 1,4-dioxane as a residual contaminant, including paints, coatings, lacquers, ethylene glycol-based antifreeze coolants, spray polyurethane foam, household detergents, cosmetics/toiletries, textile dyes, pharmaceuticals, foods, agricultural and veterinary products," as well as "magnetic tape and adhesives." *Id.* These are known and reasonably foreseen conditions of use

leading to exposures to 1,4-dioxane, and EPA's decision to ignore them when analyzing whether this chemical presents an unreasonable risk is arbitrary and capricious. EPA's theory is that it cannot regulate these impurities until it analyzes ethoxylated chemicals (*id.* at 8), but EPA provides no reasoned legal theory for why it could not act to regulate these exposures after this risk evaluation. *Id.* Even more problematically, EPA staked out the position that "EPA may choose not to include a particular impurity within the scope of any risk evaluation." 82 Fed. Reg. at 33,730. So these exposures may never be analyzed.

In addition, EPA acknowledges that 1,4-dioxane is often used as an intermediate or a reactant and that "the 1,4-dioxane would react either fully *or to a lesser extent*. Following completion of the reaction, the produced substance *may or may not be purified further*, thus removing unreacted 1,4-dioxane (if any exists). Reacted 1,4-dioxane is *assumed* to be destroyed and is thus not expected to be released or cause potential worker exposures." *See* 1,4-Dioxane, Scope at p.56, Docket ID: EPA-HQ-OPPT-2016-0723 (emphases added). But EPA never acknowledges that the unreacted 1,4-dioxane could lead to exposure. And that document provides no explanation, documentation, or quantification supporting the underlying assumption that 1,4-dioxane is destroyed or reacted. Indeed, from the description, it seems clear that it often will not be destroyed. The assumption in the last quoted sentence is contrary to the statements made in the proceeding sentences.

EPA's scopes should indicate that it will assess the reasonably available information on hazards and exposures for the substances (see Section II below), and that information should inform EPA's evaluation of the risks associated with "the conditions of use." If there is a real-world exposure, then EPA should not ignore it.

II. EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA §§ 4 and 8 to obtain additional information.

TSCA orders EPA to consider "available" and "reasonably available" information in crafting a risk evaluation, 15 U.S.C. §§ 2605(b)(4)(F)(i), 2625(k), and under the new risk evaluation rule, EPA defined "[r]easonably available information" to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 C.F.R. § 702.33, promulgated at 82 Fed. Reg. 33,748 (July 20, 2017). Thus, under its own rule, EPA has to consider information that it "can reasonably generate, obtain, and synthesize."

Yet, the scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is *reasonably* available information.

A. Any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities.

EPA must promulgate reasonable regulations under § 8(d) and 8(a) to obtain information about hazards, exposures, and conditions of use for these ten chemicals; EPA should also exercise its authority under § 8(c) to obtain additional information. Consistent with TSCA § 8(a)(5), EPA can take steps to reduce unnecessary and duplicative reporting. Because TSCA requires EPA to produce robust risk evaluations that reflect "reasonably available" information, and information available under these authorities is "reasonably available" on its face, EPA must use these authorities to fulfill its duty. Moreover, these first ten risk evaluations are crucial to establishing the credibility of the TSCA program under the Lautenberg Act, and EPA can only establish that credibility by using its full authority to obtain "reasonably available information" on chemicals, as required by the law. Collecting this information is also necessary to fulfill EPA's duty to use the best available science under TSCA § 26.

TSCA § 8(d) allows EPA to "require any person who manufactures, processes, or distributes in commerce *** any chemical substance or mixture *** to submit to the Administrator—lists of health and safety studies: (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person; or (C) reasonably ascertainable by such person." 15 U.S.C. § 2607(d). EPA should issue § 8(d) rules for these ten chemicals. To obtain a complete picture, EPA should expressly require both manufacturers and processors to report on these chemicals under the § 8(d) rules. *See* 40 C.F.R. § 716.5(c).

EPA has previously issued such rules for some of these chemicals, but two decades have passed since the last of those rules sunsetted, so new, additional health and safety studies are almost certainly available. For example, the methylene chloride and asbestos reporting periods sunsetted in 1992, the HBCD reporting period sunsetted in 1995, and the perchloroethylene reporting period sunsetted in 1997. *See* 40 C.F.R. § 716.120. Given scientific advancement over the last two decades, issuing new rules calling in health and safety studies would likely provide EPA with additional valuable information to assess the hazards, exposures, and risks posed by these chemicals. It appears that EPA has never issued such rules for Carbon Tetrachloride, Trichloroethylene, Pigment Violet 29, 1-Bromopane, 1-4 Dioxane, and N-Methylpyrrolidone. *See* 40 C.F.R. § 716.120. Thus, issuing § 8(d) rules for those chemicals is even more important.

Notably, EPA's regulations correctly interpret "health and safety study" broadly to incorporate "[a]ny data that bear on the effects of a chemical substance on health or the environment." 40 C.F.R. § 716.3. These include numerous tests for health and environmental effects. *See id.* They also include monitoring data and other assessments of human and environmental exposures. *See id.* EPA should also review these studies upon receipt and request underlying data under 40 C.F.R. §§ 716.10(a)(4), 716.40(a). EPA should also separately request reporting on these chemicals when they are manufactured, processed, or distributed as an impurity, 40 C.F.R. § 716.20(a)(9), because impurities may be an important source of exposure and thus risk, as explained above.

Under TSCA § 8(a), EPA may require manufacturers and processors to provide extensive information. *See* 15 U.S.C. § 2607(a)(2). EPA "shall, to the extent feasible" "not require reporting which is unnecessary or duplicative" and also "apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title." *Id.* § 2607(a)(5). To avoid duplication, EPA need not request reporting on information EPA has already obtained through other recent submissions such as through the Chemical Data Reporting (CDR) process. *See* 40 C.F.R. Part 711. But the CDR process does not require manufacturers and processors to provide all information that EPA can reasonably obtain under TSCA § 8(a) which is relevant to the risk evaluations. For example, EPA should require reporting of: "[a]ll existing information concerning the environmental and health effects of" each chemical; "the byproducts resulting from the manufacture, processing, use, or disposal of each" chemical; more detailed information about exposures to these chemicals, including the duration, frequency, and timing of exposures; and additional information about disposal. *See* 15 U.S.C. § 2607(a)(2). In particular, EPA can require submission of any data available on releases or exposures in the workplace and environment, and those data would be crucially important to an accurate risk evaluation. To decrease the burden on industry, EPA should pursue both rulemakings simultaneously, and EPA can provide that when information is submitted under one rule, the same information need not be submitted under the other. But EPA should use both authorities to ensure that it does not miss any information that may fall within one authority but not the other.

In addition, EPA should rely on its request authority under TSCA § 8(c). Under TSCA § 8(c), "[a]ny person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture." 15 U.S.C. § 2607(c). EPA promulgated rules governing this recordkeeping requirement at 40 C.F.R. Part 717. The rules apply to most manufacturers and many processors. 40 C.F.R. § 717.5. Manufacturers and processors must maintain records of many types of allegations, as detailed in 40 C.F.R. §§ 717.5 and 717.10. The regulation defines "significant adverse reactions" to include, but not be limited to, many specific types of harm that are highly relevant to the ultimate question presented in a risk evaluation: "whether a chemical substance presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(b)(4)(A). Firms must maintain these records for 30 or 5 years, depending on the circumstances. 40 C.F.R. § 717.15(d).

EPA should use its authority to request these records on alleged significant adverse reactions caused by the ten chemicals analyzed in the scope documents and add them to the administrative record for the relevant chemical. EPA can request records from manufacturers and processors that reported the chemicals in response to any § 8(a) and 8(d) rules or in response to CDR reporting. *Id.* § 717.17. EPA can request those records by letter. *Id.* § 717.17(b). Finally, EPA can also notify all people holding such records to provide them by a notice in the Federal Register. *Id.* These records may provide valuable information on hazards, exposures, and conditions of use, since the records may reveal not only significant adverse reactions but also information about the specific exposure and use that may have caused the reaction.

B. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps.

EPA should make robust use of its § 4 authority to fill any gaps in information. EDF recognizes that time constraints apply to these first ten chemicals and thus some types of testing may not be possible, but going forward, EPA needs to use its authority fully and do so in a timeframe that ensures it will have all of the information it needs to conduct risk evaluations.

As EPA moves forward on the first 10 risk evaluations, it should first clearly identify *all* significant information gaps on hazards or exposures. Based on its own regulation, EPA must then use its authority under TSCA § 4(a)(2) to require the development of new information to fill those gaps wherever possible. Information that EPA can generate under TSCA § 4(a)(2) is reasonably available under EPA's own regulation as "information that EPA *** can reasonably generate [and] obtain *** for use in risk evaluations." 40 C.F.R. § 702.33. Thus, EPA should identify such information gaps and then promptly require the conduct of all testing that can be done and still meet the statutory deadlines for the risk evaluations.

TSCA § 4(a)(2) provides that EPA "may, by rule, order, or consent agreement require the development of new information relating to a chemical substance *** if the Administrator determines that the information is necessary *** to perform a risk evaluation under section 6(b)." 15 U.S.C. § 2603(a)(2)(A)(i). Congress provided this additional testing authority allowing EPA to require testing or other data development efforts solely upon a determination "that the information is necessary *** to perform a risk evaluation under section 6(b)." *Id.* In light of deadlines, EPA can and should use its order authority and does not need to make the additional findings required for a rule under TSCA § 4(a)(1).

In places in these scopes, EPA seems to be going out of its way to avoid using its information authorities. For example, in numerous places in these scopes, with respect to exposure, EPA indicates that "[f]or conditions of use where data are limited or not available, [it will] review existing exposure models that may be applicable in estimating exposure levels" (p.43). This language suggests that EPA will simply default to models rather than use its authority to get needed information. In EDF's view, EPA should first use its authorities under TSCA §§ 8 and 4 to fill those information gaps, rather than rely on models to compensate for lack of information. This is not to say that exposure models do not have a role, but they are not a basis for avoiding the obligation to collect information.

Our review of the scopes indicates that there are significant gaps in the information. Where possible EPA needs to fill those gaps. When it is not possible, consistent with TSCA § 26, EPA needs to identify those gaps and characterize the uncertainty in the draft risk evaluations. To cite just one example, in the scope for Methylene Chloride EPA completely fails to mention an information gap earlier identified in the Work Plan. Specifically, the 2014 Work Plan Assessment for Methylene Chloride identified both developmental neurotoxicity and immunotoxicity from chronic exposure as important data gaps, impacting the selection of the point of departure:

> There is uncertainty about chronic exposure impacts on the nervous system function. The nervous system has been well studied and identified as very sensitive for acute effects. However, there is a paucity of data on chronic neurological impacts, especially developmental neurotoxicity. Likewise, there is limited information about immunotoxicity following chronic exposure to DCM. Existing hazard studies are not sufficient for dose response analysis to provide a lower point of departure than existing adverse findings in the liver from chronic exposures."

See Methylene Chloride: Paint Stripping Use, TSCA Work Plan Chemical Risk Assessment at p.115, https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf

C. If EPA already has relevant information, it is reasonably available and EPA should consider it.

The strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." *See, e.g.*, Asbestos literature at p.13. But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation *** is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available, EPA must review it.

In addition, much of this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. First, historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act. Second, the Lautenberg Act greatly increased the requirements companies must meet to assert CBI claims. For example, information only qualifies for protection if the submitter asserts *and* substantiates that it has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c). Thus, even if the information once merited protection, it may no longer be confidential under the standards of TSCA § 14. Third, as a general rule, TSCA § 14(b)(2) provides that health and safety studies and information from health and safety studies are not entitled to confidential treatment, so much of this information may not be confidential under that provision.

To fulfill its duties under TSCA, EPA must review this reasonably available information and identify that which is potentially relevant to the risk evaluations. Where information is relevant, EPA should also consider whether the information meets the strict requirements for nondisclosure under TSCA § 14. If not, EPA should add it to the administrative record for review by the public. Whether or not it meets those requirements, EPA should then determine whether and how to consider the information in evaluating these chemicals. Notably, TSCA § 26(j) requires that, "subject to section 14," EPA "shall make

available to the public *** a list of the studies considered by [EPA] in carrying out each such risk evaluation, along with the results of those studies." 15 U.S.C. § 2625(j).

D. When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information.

In the literature searches, EPA sometimes states that it relied on recent assessments, and then only performed research for dates beyond those assessments. *See, e.g.*, 1,4-Dioxane, Strategy for Conducting Literature Searches for 1,4-Dioxane: Supp. File for the TSCA Scope at p.7, 9-10, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0047. EPA needs to provide a short analysis presenting its review of the prior analysis to ensure it adequately captured and addressed all reasonably available information as of the date of its publication, particularly given the expanded obligations under the Lautenberg Act. If EPA finds it was not adequate, then EPA should broaden its literature search.

III. EPA needs to take additional steps to ensure both the completeness and accuracy of the information it relies upon.

As explained above, EPA should rely on its authorities under TSCA §§ 8 and 4 to obtain all reasonably available information. Those authorities include a number of measures to ensure the accuracy and completeness of the data relied upon. To the extent EPA relies on voluntarily submitted information, EPA needs to take additional steps to ensure the accuracy and completeness of the information. Otherwise, EPA will violate TSCA § 26 by failing to make decisions "in a manner consistent with the best available science." 15 U.S.C. § 2625(h)

A. EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals.

EPA has requested in each of the scopes that industry and other stakeholders provide information. While this voluntary request was a reasonable first step towards obtaining the necessary information, EPA has failed to provide any account for how this voluntary approach to collecting information will result in EPA obtaining all "reasonably available" information as EPA has defined that term. There are several obvious problems and limitations with this voluntary approach which EPA has not even acknowledged, much less addressed.

First, a voluntary call is much less likely to produce all of the necessary information than rules mandating that affected parties provide the requested information. If manufacturers and processors are legally required to provide the information, that legal obligation provides a strong incentive for them to collect and submit all relevant information. Absent that incentive, some companies may choose to focus time and attention on other matters. Indeed, the burdens (whether one considers them heavy or light) of collecting and submitting information counsel in favor of issuing mandatory rules. *If* the process of

collecting and submitting the information is not onerous or difficult, then using rules to require the submission of the information will do little if any harm to the regulated industry, and use of rules will ensure EPA has a complete picture and increase credibility. Alternatively, to the extent that the process is onerous or difficult, it is even more important that EPA *require* the submission of the information, because otherwise those burdens will likely discourage stakeholders with relevant information from collecting and submitting the information.

Second, EPA has provided no empirical evidence establishing that this voluntary approach will result in EPA obtaining all "reasonably available" information. Unless EPA has some empirical basis for stating that the voluntary approach will allow EPA to obtain all reasonably available information that it can obtain under its legal authorities, EPA must rely on its existing authorities to obtain a complete set of information.

Indeed, EPA's prior experience with voluntary reporting provides strong evidence that a voluntary approach is unlikely to provide complete and accurate data. For example, an EPA advisory committee called for the development of nanomaterial reporting rules in 2005, but EPA instead spent several years developing and carrying out a voluntary reporting program, the Nanoscale Materials Stewardship Program (NMSP). This voluntary reporting program produced minimal information as revealed by EPA's 2009 interim report on the NMSP. Nanoscale Materials Stewardship Program, Interim Report, OPPT (Jan. 2009), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0003. "[I]n the report EPA estimated that companies provided information on only about 10 percent of the chemical substances manufactured at the nanoscale that may be commercially available in 2009." 80 Fed. Reg. 18,330, 18,334 (April 6, 2015). In 2017, over a decade after the data need was identified, EPA finally finalized a § 8(a) reporting rule to acquire the data. 82 Fed. Reg. 3641 (Jan. 12, 2017). Given the past failures of voluntary approaches, EPA should not rely on them here.

Third, manufacturers and processors of these chemicals have a vested interest in EPA finding that the chemicals do not present an unreasonable risk. A no-unreasonable-risk finding reduces the likelihood of government regulation, including potential restrictions on risky chemicals, and it may reduce any stigma they may otherwise face in the marketplace. The financial costs of regulation may ultimately be very high for some specific firms and individuals, and even if not, many firms and individuals may *believe* that the costs of regulation will be high. These companies have a "financial interest" in the outcome of these proceedings, and they are not impartial. *See, e.g.*, 28 U.S.C. § 455(b)(4) (requiring Judges to disqualify themselves in proceedings where they have a financial interest). Because of this reality and appearance of partiality, relying solely on voluntary measures decreases the credibility of these risk evaluations.

Relying solely on voluntary presentation of information raises the concern that the companies or trade associations may present an incomplete or skewed picture. Companies and trade associations may choose to "cherry pick" information and provide only the information that paints their chemicals in favorable light. They may provide only summaries of information that reflect conscious and subconscious judgment calls that result in unduly favorable conclusions; and without access to the full information neither EPA nor the public can independently assess such conclusions. They may choose

not to review records robustly when the review may disclose unfavorable information. They may seek to put their best foot forward and describe the ideal scenario of use and safety measures. Or, if they have unfavorable information, they may choose not to provide any information at all and simply not participate in these proceedings.

To be sure, members of the regulated community are crucial sources of information about their chemicals' uses, hazards, and exposures, but EPA cannot simply assume that they will voluntarily disclose unfavorable or complete information about their practices and products. *See* THE FEDERALIST NO. 51 (James Madison) ("If men were angels, no government would be necessary. *** [E]xperience has taught mankind the necessity of auxiliary precautions."); *Williams v. Pennsylvania*, 136 S. Ct. 1899, 1905-06 (2016) ("Bias is easy to attribute to others and difficult to discern in oneself. *** This objective risk of bias is reflected in the due process maxim that 'no man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome.'"). Here, manufacturers and processors obviously have an interest in the outcome, and EPA must craft its procedures and approaches with that reality in mind. Requiring the submission of information is the safest approach to ensuring that these parties provide all relevant information, and that is in turn crucial to establishing and demonstrating the credibility of this process.

If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information. First, EPA can require that certain information and underlying information be provided in full, which ensures completeness. In addition, a § 8(d) rule requires that people engage in an adequate search of records. 40 C.F.R. § 716.25. Second, submitters must file certification statements by authorized officials that certify that the submitted information has been submitted in compliance with the requirements of this process. *See, e.g.*, 40 C.F.R. § 711.15(b)(1). Third, submitters often must retain records of required submissions for a period of five years, and the retention of records can help encourage accurate reporting since those records would be available should a submission latter be investigated. *See, e.g.*, 40 C.F.R. § 711.25. None of these features apply to the voluntary requests for information EPA has indicated it is relying on.

In addition, as EDF has explained in prior comments, there are numerous reasons that it is important that the public have access to full studies and the underlying information, not simply robust or other study summaries. *See, e.g.*, EDF Comments on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act, Comment at p.37, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074. Without access to full studies, the public will be challenged or unable to assess and comment on the quality of the studies used by the agency. *Id.* EDF reincorporates and reiterates the numerous points made in support of public access to the full studies here. *Id.* These points also support the importance of EPA obtaining the full studies.

B. For voluntary submissions, EPA should take additional steps to ensure completeness and accuracy and to vet information based on underlying data.

To the extent it relies on voluntary submissions, EPA can and should take additional steps to better ensure that the voluntary information it receives is accurate and complete. EPA would need to develop a far more rigorous and structured process than it currently has. For example, EPA's submission process does not appear to require anyone to certify that the information in their comments is accurate or complete to the best of their knowledge. EPA should consider approaches for vetting statements and assertions, particularly when made by entities with a financial interest in the outcome of these risk evaluations.

EPA should also request that submitters always provide full studies, as well as underlying data whenever reasonably available or obtainable. Setting aside concerns about partiality, EPA needs the underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular submission.

In addition, EPA should seek input directly from workers for manufacturers and processors, providing them an easy method to submit information on workplace practices and conditions independently from management. EPA needs to take steps to allow workers to provide input in a manner that reduces the risks of any potential retaliation from management.

To give a few specific examples from the scopes:

In the Perchloroethylene scope (also known as tetrachloroethylene or PCE), EPA cites the Vinyl Institute's comments for the fact it can be a residual or byproduct in the manufacture of other chemicals. *See* Perchloroethylene, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0732 (citing comment at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0013). That comment, in turn, contains a table claiming to summarize the approximate concentrations of Perchloroethylene in light and heavy end liquid intermediate streams yielded in the EDC/VCM process for manufacturing each of four chlorinated organic substances. The comment states that there is no residual Perchloroethylene in light liquid ends and 1.1% by typical weight in heavy liquid ends. But the comment does not provide or cite any underlying data supporting these findings. When commenters provide summary statements along these lines, EPA should give them little weight unless it also receives the underlying data to ensure that the reported results or conclusions drawn accurately reflect real-world conditions and to assess the level of certainty and scope of applicability that EPA can attribute to the results or conclusions. This point holds for all of the percentages set forth in that table, including those for the other three products.

Similar concerns arise for many of the other scopes. For example, in the Carbon Tetrachloride scope, EPA states that: "there are public comments, EPA-HQ-OPPT-2016-0733-0005 [3M] and EPA-HQ-OPPT-2016-0733-0017 [ACC], stating that carbon tetrachloride may be present in a limited number of industrial products with chlorinated ingredients at a concentration of less than 0.003% by weight." Carbon Tetrachloride, Scope at p.20, Docket ID: EPA-HQ-OPPT-2016-0733. But upon examining those

comments, they do not provide any of the underlying data or enough information to assess accuracy of the statement or the level of uncertainty that should apply to the results. The ACC comment is particularly difficult to assess. It involves multiple levels of hearsay, with ACC reporting statements that companies reported to it. Some of those companies acknowledge they are also relying on hearsay from suppliers and have not taken steps to confirm these concentrations. Those suppliers might also be relying on hearsay; it is simply not clear what the bases are for some of these values. Hearsay is, of course, particularly problematic when the statement serves the interest of the person submitting the evidence. *See, e.g.*, FED. R. EVID. P. 804(b)(5) (exception for statements against interest). As such, these concentrations arguably provide at best a "lower bound" estimate; they are not sufficient in terms of establishing that the actual concentrations are not higher. While no formal hearsay rule applies to these administrative proceedings and the hearsay evidentiary rule generally has limited applicability to technical studies and business records, it is relevant to the weight EPA should give these reported values given these circumstances. ACC does not disclose the companies providing the information, making it impossible for EPA to independently address these kinds of concerns. In addition, ACC's comment often fails to provide any clarity or detail as to how the concentrations were measured or assessed, much less provide the data underlying these claimed concentrations. The ACC comment asserts concentrations for 1,4-Dioxane, Pigment Violet 29, N-Methylpyrrolidone (NMP), Methylene Chloride (DCM), Carbon Tetrachloride, and HBCD, but for most of these concentrations, it is impossible for EPA or the public to assess whether they are accurate. For some of these concentrations, the comment states that Safety Data Sheets and Technical Data Sheets are provided with the comments, but EDF did not find any attachments with the comment containing those materials. In sum, EPA needs to scrutinize these voluntary submissions carefully and ensure access to the underlying information, which is necessary to assess the accuracy of the statements therein.

In the asbestos scoping document, EPA acknowledged that the analysis of the Chlor-Alkali industry was "primarily based on information provided by either the chlor-alkali industry or [the American Chemistry Council] and is meant to represent typical practices." *See* Asbestos, Scope at p.54, Docket ID: EPA-HQ-OPPT-2016-0736. EPA correctly recognized that EPA should "further evaluate how representative the processes witnessed at these two facilities are of processes at other plants." *Id.* at 23. EPA should take measures to ensure that its process will in fact accurately assess the full range of existing practices, relying on independent data where possible. Where independent data are unavailable, EPA should reach out to workers directly to better determine actual practices. Even when companies have good practices on paper, those practices may not be the reality on the ground.

EPA also needs to carefully scrutinize statements to ensure it correctly interprets them.

IV. These scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations.

Broadly viewed, the scopes do not meet several of the statutory requirements of TSCA. TSCA § 6(b)(4)(D) requires that EPA "shall, not later than 6 months after the initiation of a risk evaluation,

publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D). These scopes do not fully satisfy these requirements. Some aspects are plainly illegal under *any* interpretation of the statute, for the reasons given above, such as the statement that "EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11).[1] But many other aspects, while problematic, can be resolved by EPA in the next step: its development of problem formulations.

It is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. EDF believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified. With respect to susceptible populations, EPA should consider workers and, in most cases, pregnant women and children, to be potentially exposed or susceptible subpopulations. We identify below a number of specific examples where EPA's scopes are unclear and merit further study.

A. 1,4-Dioxane

EPA states: "EPA evaluated the weight of the evidence for cancer in humans and animals and concluded that 1,4-dioxane is 'likely to be carcinogenic to humans' based on evidence of carcinogenicity in several 2-year bioassays." 1,4-Dioxane, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0723. However, certain language in this section suggests that EPA may not include cancer as a hazard endpoint in the risk evaluation.

Indeed, EPA almost seems to suggest that inconclusive evidence regarding the "mode of action by which 1,4-dioxane produces liver, nasal, peritoneal (mesotheliomas) and mammary gland tumors" might form a basis for disregarding the evidence of such hazards. *Id.* at 35. As a general matter, EPA should not exclude observed hazards simply because the underlying MOA is not fully delineated or understood, doing so would significantly and inappropriately jeopardize the robustness and health-protections of the risk evaluation. If there is evidence of hazard, EPA should include it in the risk evaluation, even if the precise mode of action is not yet understood.

[1] As explained above, EPA puts too much weight on a floor statement from a single Senator, David Vitter. But even Senator Vitter stated that EPA must consider all conditions of use identified in the scope. *See* 114 Cong. Rec. S3520 (daily ed. June 7, 2016) (statement of Sen. Vitter). Despite that statement, the scoping documents all state that "during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11). Thus, EPA is inconsistent in how much weight it gives to Senator Vitter's statements, and EPA's current interpretation appears to contradict the views expressed throughout the legislative history by every single legislator. If EPA excluded uses identified in the scope, such as uses in the chlor-alkali industry (e.g., pp.20, 23-24), then EPA will be acting contrary to Senator Vitter's statement.

B. Perchloroethylene

The scope for Perchloroethylene states that "EPA expects to consider hazards identified in the recent assessment by the EPA Integrated Risk Information System (IRIS) Program: neurotoxicity, kidney toxicity, liver toxicity, developmental and reproductive toxicity and cancer. Support for an association with immune and blood effects was less well characterized." Perchloroethylene, Scope at p.11, Docket ID: EPA-HQ-OPPT-2016-0732. It is unclear from the scope whether EPA intends to include immune and blood effects in particular.

C. Trichloroethylene (TCE)

In the scope for TCE, EPA suggests that TCE's use as a spot remover will not be analyzed because it was previously analyzed in a risk evaluation. TCE, Scope at p.25, Docket ID: EPA-HQ-OPPT-2016-0737. That approach may be reasonable if EPA finalizes its proposed ban on this use of TCE to address those risks, as discussed more below. But that approach only applies to those spot remover uses that have previously been analyzed, specifically commercial dry cleaning facilities. This risk evaluation needs to consider TCE's use as a consumer spot remover. Those uses have not been analyzed in-depth, and the 2014 work plan assessment recognized that some such products may contain TCE as a main ingredient. *See* Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses, TSCA Work Plan Chemical Risk Assessment at p.52, https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

D. N-Methylpyrrolidone (NMP)

The NMP scope has numerous inconsistencies with respect to its identification of the endpoints to be assessed. EPA begins by acknowledging that a "number of human health hazards have been identified for NMP including adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems." N-Methylpyrrolidone, Scope at p.36, Docket ID: EPA-HQ-OPPT-2016-0743. EPA also states that: "EPA expects to consider all potential hazards associated with NMP." *Id.* EDF completely agrees with that approach. However, the description under section 2.42 Human Health Hazards indicates that EPA intends to focus on a narrower set of hazards (acute toxicity and reproductive/developmental toxicity), and provides no justification or even explanation for excluding some of the hazards that it previously identified.

E. Potentially exposed or susceptible subpopulations

EPA also does not identify pregnant women, women of childbearing age, or the developing fetus as potential exposed or susceptible subpopulations for either N-Methylpyrrolidone (NMP) [NMP, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0743] or TCE [TCE, Scope at pp.37-38, Docket ID: EPA-HQ-OPPT-2016-0737], despite the fact that EPA's previous risk assessments on these two chemicals identify women of childbearing age and the developing fetus as a primary susceptible population (in addition to workers). EPA's failure to identify these populations in the scopes is both contrary to law and an abuse of discretion. TSCA § 3(12) defines "potentially exposed or susceptible subpopulation" to include "a

group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance *** , such as infants, children [or] pregnant women." 15 US.C. § 2602(12). Here, EPA has previously found that "women of childbearing age" are at greater risk of adverse health effects from these chemicals. 82 Fed. Reg. 7432, 7434 (Jan. 19, 2017); 82 Fed. Reg. 7464, 7467 (Jan. 19, 2017).

Furthermore, TSCA requires that EPA identify "the potentially exposed or susceptible subpopulations the Administrator expects to consider" in the scopes. 15 US.C. § 2605(b)(4)(D). While EPA has considered those at greater risk due to *increased exposure* in the scopes to some extent, the agency appears to defer the process of identifying populations with *greater susceptibility* to the problem formulation or risk evaluation stage: "In developing the hazard assessment, EPA will also evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s)." *See, e.g.*, NMP, Scope at pp.36-37, Docket ID: EPA-HQ-OPPT-2016-0743; 1,4-Dioxane, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0723.

V. EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures.

The scoping documents generally acknowledge the need to analyze activities related to a chemical's distribution, but EPA will need to analyze these exposures more robustly than the scopes currently reflect. *See, e.g.*, 1,4-Dioxane, Scope at p.22, Docket ID: Docket ID: EPA-HQ-OPPT-2016-0723.

The scoping documents give little, if any, attention to potential releases and exposures resulting from accidental releases. EDF does not suggest that EPA needs to consider every possible scenario, but the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks. For example, as and after Hurricane Harvey passed through Houston, over 40 sites released toxic chemicals into the environment. *See, e.g.*, More Than 40 Sites Released Hazardous Pollutants Because of Hurricane Harvey, https://www.nytimes.com/interactive/2017/09/08/us/houston-hurricane-harvey-harzardous-chemicals.html?_r=0. Given the *known* accidental releases, the huge number of petrochemical plants and refineries in the Houston area, and the likelihood that flooding there may become more common in light of climate change, such events are clearly reasonably foreseen and hence EPA needs to give more consideration to the potential for accidental releases.

VI. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures.

Language used in the scopes suggests that EPA may inaccurately assume that people comply with all warning labels and always use personal protective equipment (PPE). EDF strongly urges EPA to consider real-world exposures reflecting the reality of the sometimes low-compliance with or non-existence of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by

either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). And absent empirical evidence establishing the extent to which people are using these measures, EPA should assume that they may not be. Indeed, EPA's need for accurate information about actual compliance is another reason to rely on its authorities under TSCA § 8 to mandate that manufacturers and processors provide that information. In addition, it bears noting that reliance on PPE as a primary measure to protect workers is counter to OSHA's Industrial Hygiene Hierarchy of Controls (HOC), a long-standing principle that prioritizes measures to eliminate or reduce the presence of a hazard in occupational settings (e.g., substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves, such as through reliance on PPE and warning labels. The HOC exemplifies the best available science for creating safe, healthful workplace environments.

As an example of a problematic reference to PPE in the scopes, in the asbestos scope, EPA stated that "[d]ermal exposure is unlikely due to glove use in the workplace." Asbestos, Scope at p.37, Docket ID: EPA-HQ-OPPT-2016-0736. But EPA cites no evidence supporting this assumption. While gloves may be used in many workplaces, EPA needs to provide evidence of the extent of such use. Among other things, EPA correctly noted earlier that "certain conditions of use, such as a mechanic changing asbestos-containing brakes, may also result in dermal exposure." *Id.* at 35. Is there any evidence that all or even most mechanics wear gloves when changing brakes? Indeed, EPA should identify mechanics as a relevant potentially exposed or susceptible subpopulation based on their exposure to brakes.

In comments EDF has submitted in these dockets, EDF previously commented on the serious limitations of labeling and PPE, as well as the importance of adherence to the hierarchy of controls to limit workplace exposures. *See, e.g.*, EDF comments at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0046, March 15, 2017; and at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052, November 21, 2016. EDF reincorporates and reiterates the points made in those comments here.

VII. EPA's decision not to examine uses addressed by its planned § 6(a) rules governing certain uses of TCE, DCM, and NMP is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses.

For Trichloroethylene (TCE), Methylene Chloride (DCM), and N-Methylpyrrolidone (NMP), EPA states that conditions of use previously examined will not be re-evaluated. TCE, Scope at p.9, Docket ID: EPA-HQ-OPPT-2016-0737; DCM, Scope at p.29, Docket ID: EPA-HQ-OPPT-2016-0742 ("This includes uses assessed in the U.S. EPA (2014a) risk assessment and therefore those uses are out of scope for the risk evaluation."); NMP, Scope at pp.20, 28, Docket ID: EPA-HQ-OPPT-2016-0743 ("This includes uses assessed in the previous EPA risk assessment (U.S. EPA, 2015) and therefore those uses are out of scope for the risk evaluation."). EPA has previously found these uses even by themselves present unreasonable risks to human health. In addition, these uses have the potential to increase the total

exposure of people to these chemicals. As a result, EPA can only reasonably exclude these uses if it finalizes the proposed rules to ban these uses. EDF strongly supports those bans for the reasons it articulated in its prior comments.

If EPA does not finalize these bans, then excluding these uses is both contrary to law and arbitrary and capricious. By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses *unless* EPA has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals.

* * * * *

EDF appreciates the opportunity to provide comments and EPA's consideration of them.

Environmental Defense Fund Comments on

Ten Scopes under the Toxic Substances Control Act

Docket IDs: EPA-HQ-OPPT-2016-0725 (Pigment Violet 29), EPA-HQ-OPPT-2016-0723 (1-4, Dioxane), EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene), EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride), EPA-HQ-OPPT-2016-0735 (HBCD), EPA-HQ-OPPT-2016-0736 (Asbestos), EPA-HQ-OPPT-2016-0737 (Trichloroethylene), EPA-HQ-OPPT-2016-0741 (1-Bromopropane), EPA-HQ-OPPT-2016-0742 (Methylene Chloride), and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone)

Submitted Tuesday September 19, 2017

The Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the scopes for the risk evaluations for the first ten chemicals being evaluated under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

In addition to specific comments on each chemical, EDF is providing broad comments addressing the scopes of risk evaluations for the first 10 chemicals as well as others in the future. While our comments are broadly applicable to all of the scope documents, we include examples from specific scopes to illustrate flaws and limitations.

As explained below, these scopes deviate from certain requirements of the law and in places are too unclear and vague or ambiguous to allow us to provide definitive comments. EDF recognizes that EPA was working under tight deadlines in producing these scopes – a problem it further exacerbated by EPA's decision to make major, late changes to the risk evaluation rule. EPA should take advantage of the upcoming problem formulation stage to address the many problems we identify below, and to more clearly and transparently explain its plans for these risk evaluations.

Before discussing the merits of the scoping documents, EDF provides the following clarification about its citation approach. Each scoping document contains largely identical, boilerplate language providing the agency's overall legal approach to "conditions of use" as well as its approaches on some other issues. Indeed, each document includes the same typos or misquotes of the underlying law. For ease of reference and to reduce excessive citations, EDF quotes from the asbestos scoping document and provides simply the page number when addressing these broader legal problems that are present in each scoping document. These comments equally apply to all scoping documents since they all contain

this same language; the only difference is page number. When EDF is specifically quoting another scoping document, we provide a citation clarifying that point.

Contents:

I. TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use.

EPA's scoping documents (pp.11-13) state that EPA has determined that "certain activities may not generally be considered to be conditions of use" (p.11) and also that EPA may "exclude certain activities that EPA has determined to be conditions of use" (p.12). EPA's approach asserts that EPA is allowed to ignore numerous circumstances falling within the statutory definition of "conditions of use" and is contrary to law. For the current set of chemicals under review, EPA may well be ignoring circumstances leading to ongoing exposures, and as a result, will fail to evaluate the risks the chemicals actually pose to human health and the environment.

TSCA's language and structure unambiguously foreclose EPA's interpretation. EPA's decision to disregard certain uses and exposures is also "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to consider "factors which Congress has not intended it to consider [and] entirely fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, as the scoping documents themselves reveal, this approach leads to irrational and arbitrary applications. Instead, EPA should be guided by the statutory language and consider all of those circumstances falling within the definition of "conditions of use." EPA should evaluate all of the circumstances revealed by the evidence of use and exposure, not ignore evidence because of self-imposed blinders.

A. The plain text, overall structure, purpose, and legislative history of TSCA indicate that EPA has to determine whether a chemical substance presents an unreasonable risk comprehensively, under all of its conditions of use.

i) *The plain text requires EPA to consider all conditions of use.*

Statutory interpretation should begin, as always, with the language of the statute. The plain language of both the risk evaluation provision and the definition of conditions of use support the interpretation that EPA must consider all circumstances falling within the statutory definition of "conditions of use." The main risk evaluation provision, TSCA § 6(b)(4)(A), directs that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). Inserting the statutory definition of conditions of use, this provision provides that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* §§ 2605(b)(4)(A), 2602(4). Thus, EPA has to analyze the risks of a substance under the circumstances described in the definition of "conditions of use," and no qualifying language allows EPA to exclude circumstances within that definition. The clause "as determined by the Administrator" calls for a factual finding or determination to be made by EPA. The relevant dictionary definition of "determine" is to "ascertain or establish exactly, typically as a result of research or calculation." OXFORD

AMERICAN DICTIONARY 474 (3d ed. 2010). While EPA may exercise reasonable judgment when interpreting "reasonably foreseen," nothing in this language grants EPA discretion to *ignore* factual circumstances that fall within the definition of "conditions of use." Indeed, statutes often direct agencies "to determine" things or make "determinations," and it is understood that the agency must make the finding required by the statutory language.

EPA's position that it can ignore known and foreseeable uses violates the text of the law. In the scoping documents, EPA asserts that it may ignore "legacy uses" and "associated disposals," impurities, alleged "de minimis" exposures, intermediates, conditions of use within closed systems, and conditions of use that have been analyzed by another regulatory agency (p.12). But "conditions of use" expressly includes "the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen to be to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). And every one of those circumstances is a "known" or "reasonably foreseen" "manufacture", "process[ing]," "use," or "disposal of" a chemical substance. Congress expressly chose to define "conditions of use" broadly to include not only "intended," but also "known" or "reasonably foreseen" manufacture, processing, distribution, use, and disposal. 15 U.S.C. § 2602(4). Disregarding chemical substances present as impurities or byproducts in the scoping documents, for example, because they are not "intended" essentially reads the other two scenarios out of the statute. Similarly, all the other identified conditions of use are also "intended, known, or reasonably foreseen." For example, EPA's scope suggests that 90% of the domestic production of Pigment Violet 29 "is processed as a site-limited intermediate." Pigment Violet 29, Scope at p.19, Docket ID: EPA-HQ-OPPT-2016-0725. It would absurd to ignore these intermediate uses when analyzing this chemical; doing so will lead to a truncated and incomplete analysis. Similarly the decision to exclude 1,4-dioxane's presence in numerous consumer, commercial, and industrial products as a byproduct of ethoxylation is entirely inappropriate, and will result in deficient and erroneous evaluation and determination of the chemical substance's risks. The same points can be made for many of the other chemicals used as intermediates or present as byproducts of chemical or product manufacture.

In contrast to the correct interpretation, EPA's new interpretation finds no support in the text. In the final risk evaluation rule (82 Fed. Reg. 33,726, 33,729 (July 20, 2017)), the only statutory textual basis for EPA's theory appears to be the "expects to consider" clause in the scope provision, TSCA § 6(b)(4)(D), requiring EPA to "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator *expects to consider*." 15 U.S.C. § 2605(b)(4)(D). But "expects to consider" does not mean "chooses to consider" or "prefers to consider." It is not the language of discretion; it is temporal language of anticipation or prediction. The dictionary definition of "to expect" is to "regard (something) as likely to happen." OXFORD AMERICAN DICTIONARY 609 (3d ed. 2010). This language indicates that, in the scope, EPA should describe what it anticipates studying, but it does not state that EPA has discretion to choose to ignore intended, known, or reasonably foreseen uses, hazards, or exposures. Moreover, the provision dictating what EPA must consider during a risk evaluation does not limit EPA's analysis to conditions of use identified in the scope. 15 U.S.C. § 2605(b)(4)(F). Indeed, EPA must consider all such conditions to fulfill its requirement that EPA account for the "likely duration, intensity, frequency, and

number of exposures under the conditions, where relevant." 15 U.S.C. 2605(b)(4)(F)(iv). Thus, the statutory language does not support EPA's assertion of discretion, including EPA's decision to limit its analyses to those factors identified in each scope. For example, under the rule of the last antecedent, the phrase "the Administrator expects to consider" does not even *modify* "conditions of use" or "hazards" or "exposures." Notably, EPA has so little regard for the statutory language that it repeatedly misquotes this language in significant ways.

Textually, EPA's argument also directly conflicts with TSCA § 26(k). 15 U.S.C. § 2625(k). TSCA § 26(k) requires EPA to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." *Id.* Notably, this requirement does not include *any* conditional phrase that modifies "conditions of use." And Congress included this provision to ensure that EPA could not ignore "reasonably available" "information relating to a chemical substance or mixture"; the purpose of this provision is to compel EPA to consider all reasonably available information. It would undermine this directive if EPA chooses to arbitrarily ignore certain uses and related exposures.

ii) *TSCA's overall structure requires EPA to consider all of the conditions of use.*

TSCA provisions direct EPA to prepare risk evaluations and the related findings for "chemical substances," *as a whole*, not for specific or limited conditions of use of those substances. For example, the risk management provision expressly requires EPA to address risks when the risks arise from combined exposure. TSCA § 6(a) provides that: "If [EPA] determines in accordance with [the risk evaluation provision] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, *or that any combination of such activities*, presents an unreasonable risk of injury to health or the environment," then EPA must issue a risk management rule. 15 U.S.C. § 2605(a); *see also* 15 U.S.C. § 2608(a) (using same language in provision governing requests to other federal agencies to address risks). Thus, if "any combination" of conditions of use presents an unreasonable risk, EPA must issue a risk management rule. But EPA must analyze *all* of these activities to assess whether *any combination* presents a risk.

When describing the end of a risk evaluation, TSCA requires EPA to make a finding about the "chemical substance" with no reference to conditions of use. *See, e.g.*, 15 U.S.C. § 2605(c)(1), (*i*) ("If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A)," then EPA must issue a regulation to address the unreasonable risk.). The absence of any reference to conditions of use makes it clear that EPA must make a finding for a chemical substance as a whole, not one limited to certain conditions of use. Notably, in the final prioritization rule, EPA correctly reasoned that this type of language indicated that EPA had to consider *all* uses in prioritization. *See* 82 Fed. Reg. 33,753, 33,755 (July 20, 2017) ("The statute directs EPA to make prioritization determinations on a 'chemical substance' or 'substance,' not on 'uses,' *see, e.g.*, 15 U.S.C. §§ 2605(b)(1)(A)-(C), and in most cases, without reference to 'the conditions of use.'"). This reasoning equally applies to risk evaluations.

iii) *TSCA's purpose, as well as basic logical reasoning and the best available science, require EPA to consider all conditions of use to assess a chemical substance as a whole.*

The purpose of the risk evaluation is to analyze the risks of a substance based on an assessment of its hazards and exposures. Ignoring potential exposures at the outset undermines that purpose. And science and logic do not support EPA's exceptions. For example, EPA states that it may disregard so-called "de minimis" exposures from conditions of use that occur in a closed system or use as an intermediate (p.12). But intermediates are often not completely consumed in chemical reactions and may remain as a residual in final reaction products. *See, e.g.*, California Department of Toxic Substances Control, Spray Polyurethane Foam Systems Containing Unreacted Methylene Diphenyl Diisocyanates, http://www.dtsc.ca.gov/SCP/Spray_Polyurethane_Foam.cfm (last visited Sept. 18, 2017). So the presumption that intermediates lead to a "de minimis" exposure is often contrary to the scientific evidence. In addition, intermediates must still be manufactured as well as typically being stored, transferred, or distributed, all of which are activities that can lead to exposures – including to workers, whom TSCA expressly identifies as a "potential exposed or susceptible subpopulation." Similarly, unintended impurities or contaminants can nonetheless lead to exposures and hence risks to human health or the environment, the significance of which needs to be determined in conducting a risk evaluation. *See infra* at pp.10-11 (discussing 1,4-dioxane). Ignoring them at the outset is contrary to the purpose of TSCA and risk evaluations, as well as the law's requirement that EPA rely on the best available science.

To be sure, EDF generally agrees with EPA's statement that "all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk." 82 Fed. Reg. at 33,734. Legally, EPA may be able to provide a concise and scientifically valid finding that a particular condition of use—such as the use phase of a chemical used as an intermediate—leads to little or no exposure and risk in a particular case, based on less than an in-depth analysis. And TSCA does not require a quantitative evaluation when a qualitative evaluation is determined and documented to be appropriate. But TSCA does not authorize EPA to simply "exclude" conditions of use at the outset as a matter of legal discretion. Furthermore, EPA must provide a scientific, data-backed rationale for why it decides a less extensive evaluation is sufficient, and cannot merely rely on a lack of data for such a decision.

EPA is imposing blinders on its analysis by asserting its authority to refuse to look at certain conditions of use, including known uses and disposals, and the result is that EPA is overlooking exposures in the real world. This approach is both contrary to law and arbitrary and capricious, as explained *infra* at Part I.D.

iv) *The legislative history does not justify or even lend support to EPA's approach.*

To justify its new position, EPA has emphasized the "legislative history" (p.11). But the legislative history, read as a whole, does not support EPA's approach. In the risk evaluation rule, EPA claims that the "legislative history of the amended TSCA *** explicitly states that the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation." 40 Fed. Reg. at 33,728 (citing 114 Cong. Rec. S3519-20 (daily ed. June 7, 2016) (statement of Sen. Vitter)). EPA relies on a floor

statement from a single Senator, which is one of the least illuminating forms of legislative history. EPA ignores that the rest of the legislative history reveals that other Senators thought that the statutory language would require EPA to consider all conditions of use in risk evaluations under the Lautenberg Act. Four principal Democratic negotiators of the legislation submitted a statement to the record that: "[t]he definition of 'conditions of use' described above plainly covers all uses of a chemical substance." 114 Cong. Rec. S3516 (daily ed. June 7, 2016). Similarly, when explaining why the bill expressly "grandfathered" in prior risk assessments (such as for Methylene Chloride), these negotiators explained that the provision was necessary because those "risk assessments for these chemicals were not conducted across all conditions of use." *Id.* at S3519. This explanation clearly reflects that *future* risk evaluations under TSCA would have to be conducted "across all conditions of use."

Unlike the text and structure of TSCA, the legislative history is somewhat ambiguous at points, although, if anything, it supports the position that EPA must consider "all conditions of use" since more Senators expressed that view and they did so in a formal statement.

B. Conditions of use expressly include certain so-called legacy uses and associated disposals.

In each of the scopes EPA stated that it *will* exclude so-called "legacy uses" and "associated disposal," (p.12) and EPA appears to rely on its reasoning from the risk evaluation rule. 82 Fed. Reg. at 33,729-30. EPA has asserted that no statutory text addresses this issue, and EPA stated that the use of the phrase "to be" in the definition of "conditions of use" implies a prospective application. 82 Fed. Reg. at 33,730; *see* 15 U.S.C. § 2602(4) (defining conditions of use to "mean[] the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen *to be* manufactured, processed, distributed in commerce, used, or disposed of") (emphasis added). EPA also (inaccurately) asserted that it did "not have an effective tool to address risks found to arise from uses in consumer settings if there" is no on-going manufacture, processing, or distribution. 82 Fed. Reg. at 33,730. But none of this reasoning survives scrutiny.

EPA's argument based on tense clearly does not apply to the legacy uses and associated disposals. If a chemical substance is present in a product or material that an industrial, commercial, or residential consumer is still using, then the substance is known "to be" used in that circumstance. Similarly, if a substance has not been disposed of yet, its disposal is in the future and reasonably foreseeable. As a result, these "legacy uses" and "associated disposal[s]" fall squarely within TSCA's definition of "conditions of use," which includes the "circumstances *** under which a chemical substance is *** known *** to be *** used, or disposed of." 15 U.S.C. § 2602(4). EPA has presented no textual basis for treating the first three participles in the list in this definition (manufactured, processed, and distributed in commerce) differently than the last two participles (used and disposed of).

EPA's theory that § 6 focuses on the "continuing flow of chemical substances" in "their lifecycles" (p.12) completely ignores that the use and disposal of a chemical is *part* of the lifecycle of a chemical, as defined by Congress in TSCA. Indeed, chemicals that are still in use are still "distributed in commerce" as that term is defined in TSCA. 15 U.S.C. § 2602(5). In the final risk evaluation rule, EPA stated that it

"believes the statute is better interpreted to focus on the prospective flow of the chemical substance," 80 Fed. Reg. at 33,730, but Congress expressly covered substances *after* their introduction into commerce as well.

EPA also justified its decision to ignore legacy uses by claiming it lacks tools to address risks from uses in consumer settings if there is no on-going commercial manufacture, processing, or distribution. 80 Fed. Reg. at 33,730. But TSCA § 6(a) expressly provides EPA with authorities that could manage some of these risks, even if it does not provide as broad authority as it does over manufacturers and processors. *See* 15 U.S.C. § 2605(a). For example, at risk management, EPA may impose "[a] requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture." *Id.* § 2605(a)(5). For example, EPA could ban the sale or future use of products containing a chemical even if that chemical is no longer in production in the United States, or EPA could require that such items be labeled. EPA may also impose "[a] requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or *by any other person* who uses, or disposes of, it for commercial purposes." *Id.* § 2605(a)(6)(A) (emphasis added).

In any event, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Indeed, in order to assess real-world risks of a chemical using the best available science, EPA needs to consider even those exposures over which it has limited or shared control. This approach is particularly appropriate given TSCA § 9's referral provisions.

C. The text and overall structure of TSCA makes it clear that EPA has to analyze uses, even if they have been assessed by another agency or are within another agency's jurisdiction.

EPA also stated that it may "exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risk" (p.12). But EPA provides no textual basis for ignoring those uses, which are often "circumstances *** under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Nothing in the risk evaluation provision or definition of conditions of use authorizes EPA to ignore conditions of use because of other agencies' jurisdiction over chemical substances. And several other provisions of TSCA indicate that Congress intended for EPA to consider such exposures, except to the extent Congress explicitly provided otherwise.

First, TSCA § 9(a) provides a detailed procedural mechanism for EPA under certain circumstances to request for another federal agency to address an unreasonable risk arising from a chemical substance that EPA has identified. 15 U.S.C. § 2608(a). This request then triggers a number of duties for both EPA and the other agency, requiring one of the two agencies to take action to address the risk. Thus Congress intended for EPA to prepare risk evaluations analyzing uses that might be addressed by another agency, and Congress created a substantive and procedural mechanism to resolve overlapping jurisdiction only *after* completing the risk evaluation. If EPA could just ignore risks arising from

conditions of use that fall within other agencies' jurisdiction, or if Congress meant for EPA to defer to those agencies' current regulatory approach to those chemicals at the outset before conducting a risk evaluation, then EPA might never make the finding that triggers the § 9(a) process. Here again, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Given that Congress expressly addressed the issue of overlapping regulatory jurisdictions in TSCA § 9, EPA cannot avoid those procedures by simply ignoring uses that fall within another agency's jurisdiction. Furthermore, EPA is expressly required to evaluate exposures from combinations of activities, which it cannot do if it excludes conditions of use at the outset that have been evaluated or regulated by another agency, particularly when that risk management is not an outright ban.

Second, Congress expressly exempted certain regulated chemicals or uses of chemicals from EPA's authority when it defined "chemical substance" in TSCA § 3(2). 15 U.S.C. § 2602(2)(B). For example, "chemical substance" does not include certain materials as defined in the Atomic Energy Act of 1954. *See id.* § 2602(2)(B)(ii), (iv). Thus, when Congress intended for EPA not to regulate certain conditions of use because they were regulated under other specific federal statutes, Congress expressly excluded those conditions of use. That Congress chose a limited, specific set of exclusions indicates that Congress did not intend for EPA generally to ignore other conditions of use even where they fall under other federal regulatory schemes.

D. The scopes contain incoherent and arbitrary and capricious reasoning because of EPA's approach to conditions of use.

EPA's illegal approach to "conditions of use" leads it to put "blinders" on regarding certain uses, exposures, and risks. The result is "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to have considered "factors which Congress has not intended it to consider [and] entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. It also violates several provisions of TSCA § 26 because by ignoring uses, exposures, and related information, EPA will not be acting "consistent with the best available science," EPA will not base decisions on "on the weight of the scientific evidence," and EPA will not "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h), (*i*), (k). In addition, because EPA's distinction is a false one untethered to the information, EPA seems to treat certain conditions of use inconsistently throughout the documents.

For example, in the 1,4-dioxane scope, EPA states that it will not consider risks arising from 1,4-dioxane when it is present as a by-product or residual contaminant from the manufacture of other chemicals. *See* 1,4-Dioxane, Scope at p.21, Docket ID: EPA-HQ-OPPT-2016-0723. But EPA identifies numerous products that "potentially contain[] 1,4-dioxane as a residual contaminant, including paints, coatings, lacquers, ethylene glycol-based antifreeze coolants, spray polyurethane foam, household detergents, cosmetics/toiletries, textile dyes, pharmaceuticals, foods, agricultural and veterinary products," as well as "magnetic tape and adhesives." *Id.* These are known and reasonably foreseen conditions of use

leading to exposures to 1,4-dioxane, and EPA's decision to ignore them when analyzing whether this chemical presents an unreasonable risk is arbitrary and capricious. EPA's theory is that it cannot regulate these impurities until it analyzes ethoxylated chemicals (*id.* at 8), but EPA provides no reasoned legal theory for why it could not act to regulate these exposures after this risk evaluation. *Id.* Even more problematically, EPA staked out the position that "EPA may choose not to include a particular impurity within the scope of any risk evaluation." 82 Fed. Reg. at 33,730. So these exposures may never be analyzed.

In addition, EPA acknowledges that 1,4-dioxane is often used as an intermediate or a reactant and that "the 1,4-dioxane would react either fully *or to a lesser extent*. Following completion of the reaction, the produced substance *may or may not be purified further*, thus removing unreacted 1,4-dioxane (if any exists). Reacted 1,4-dioxane is *assumed* to be destroyed and is thus not expected to be released or cause potential worker exposures." *See* 1,4-Dioxane, Scope at p.56, Docket ID: EPA-HQ-OPPT-2016-0723 (emphases added). But EPA never acknowledges that the unreacted 1,4-dioxane could lead to exposure. And that document provides no explanation, documentation, or quantification supporting the underlying assumption that 1,4-dioxane is destroyed or reacted. Indeed, from the description, it seems clear that it often will not be destroyed. The assumption in the last quoted sentence is contrary to the statements made in the proceeding sentences.

EPA's scopes should indicate that it will assess the reasonably available information on hazards and exposures for the substances (see Section II below), and that information should inform EPA's evaluation of the risks associated with "the conditions of use." If there is a real-world exposure, then EPA should not ignore it.

II. EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA §§ 4 and 8 to obtain additional information.

TSCA orders EPA to consider "available" and "reasonably available" information in crafting a risk evaluation, 15 U.S.C. §§ 2605(b)(4)(F)(i), 2625(k), and under the new risk evaluation rule, EPA defined "[r]easonably available information" to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 C.F.R. § 702.33, promulgated at 82 Fed. Reg. 33,748 (July 20, 2017). Thus, under its own rule, EPA has to consider information that it "can reasonably generate, obtain, and synthesize."

Yet, the scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is *reasonably* available information.

A. Any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities.

EPA must promulgate reasonable regulations under § 8(d) and 8(a) to obtain information about hazards, exposures, and conditions of use for these ten chemicals; EPA should also exercise its authority under § 8(c) to obtain additional information. Consistent with TSCA § 8(a)(5), EPA can take steps to reduce unnecessary and duplicative reporting. Because TSCA requires EPA to produce robust risk evaluations that reflect "reasonably available" information, and information available under these authorities is "reasonably available" on its face, EPA must use these authorities to fulfill its duty. Moreover, these first ten risk evaluations are crucial to establishing the credibility of the TSCA program under the Lautenberg Act, and EPA can only establish that credibility by using its full authority to obtain "reasonably available information" on chemicals, as required by the law. Collecting this information is also necessary to fulfill EPA's duty to use the best available science under TSCA § 26.

TSCA § 8(d) allows EPA to "require any person who manufactures, processes, or distributes in commerce *** any chemical substance or mixture *** to submit to the Administrator—lists of health and safety studies: (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person; or (C) reasonably ascertainable by such person." 15 U.S.C. § 2607(d). EPA should issue § 8(d) rules for these ten chemicals. To obtain a complete picture, EPA should expressly require both manufacturers and processors to report on these chemicals under the § 8(d) rules. *See* 40 C.F.R. § 716.5(c).

EPA has previously issued such rules for some of these chemicals, but two decades have passed since the last of those rules sunsetted, so new, additional health and safety studies are almost certainly available. For example, the methylene chloride and asbestos reporting periods sunsetted in 1992, the HBCD reporting period sunsetted in 1995, and the perchloroethylene reporting period sunsetted in 1997. *See* 40 C.F.R. § 716.120. Given scientific advancement over the last two decades, issuing new rules calling in health and safety studies would likely provide EPA with additional valuable information to assess the hazards, exposures, and risks posed by these chemicals. It appears that EPA has never issued such rules for Carbon Tetrachloride, Trichloroethylene, Pigment Violet 29, 1-Bromopane, 1-4 Dioxane, and N-Methylpyrrolidone. *See* 40 C.F.R. § 716.120. Thus, issuing § 8(d) rules for those chemicals is even more important.

Notably, EPA's regulations correctly interpret "health and safety study" broadly to incorporate "[a]ny data that bear on the effects of a chemical substance on health or the environment." 40 C.F.R. § 716.3. These include numerous tests for health and environmental effects. *See id.* They also include monitoring data and other assessments of human and environmental exposures. *See id.* EPA should also review these studies upon receipt and request underlying data under 40 C.F.R. §§ 716.10(a)(4), 716.40(a). EPA should also separately request reporting on these chemicals when they are manufactured, processed, or distributed as an impurity, 40 C.F.R. § 716.20(a)(9), because impurities may be an important source of exposure and thus risk, as explained above.

Under TSCA § 8(a), EPA may require manufacturers and processors to provide extensive information. *See* 15 U.S.C. § 2607(a)(2). EPA "shall, to the extent feasible" "not require reporting which is unnecessary or duplicative" and also "apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title." *Id.* § 2607(a)(5). To avoid duplication, EPA need not request reporting on information EPA has already obtained through other recent submissions such as through the Chemical Data Reporting (CDR) process. *See* 40 C.F.R. Part 711. But the CDR process does not require manufacturers and processors to provide all information that EPA can reasonably obtain under TSCA § 8(a) which is relevant to the risk evaluations. For example, EPA should require reporting of: "[a]ll existing information concerning the environmental and health effects of" each chemical; "the byproducts resulting from the manufacture, processing, use, or disposal of each" chemical; more detailed information about exposures to these chemicals, including the duration, frequency, and timing of exposures; and additional information about disposal. *See* 15 U.S.C. § 2607(a)(2). In particular, EPA can require submission of any data available on releases or exposures in the workplace and environment, and those data would be crucially important to an accurate risk evaluation. To decrease the burden on industry, EPA should pursue both rulemakings simultaneously, and EPA can provide that when information is submitted under one rule, the same information need not be submitted under the other. But EPA should use both authorities to ensure that it does not miss any information that may fall within one authority but not the other.

In addition, EPA should rely on its request authority under TSCA § 8(c). Under TSCA § 8(c), "[a]ny person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture." 15 U.S.C. § 2607(c). EPA promulgated rules governing this recordkeeping requirement at 40 C.F.R. Part 717. The rules apply to most manufacturers and many processors. 40 C.F.R. § 717.5. Manufacturers and processors must maintain records of many types of allegations, as detailed in 40 C.F.R. §§ 717.5 and 717.10. The regulation defines "significant adverse reactions" to include, but not be limited to, many specific types of harm that are highly relevant to the ultimate question presented in a risk evaluation: "whether a chemical substance presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(b)(4)(A). Firms must maintain these records for 30 or 5 years, depending on the circumstances. 40 C.F.R. § 717.15(d).

EPA should use its authority to request these records on alleged significant adverse reactions caused by the ten chemicals analyzed in the scope documents and add them to the administrative record for the relevant chemical. EPA can request records from manufacturers and processors that reported the chemicals in response to any § 8(a) and 8(d) rules or in response to CDR reporting. *Id.* § 717.17. EPA can request those records by letter. *Id.* § 717.17(b). Finally, EPA can also notify all people holding such records to provide them by a notice in the Federal Register. *Id.* These records may provide valuable information on hazards, exposures, and conditions of use, since the records may reveal not only significant adverse reactions but also information about the specific exposure and use that may have caused the reaction.

B. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps.

EPA should make robust use of its § 4 authority to fill any gaps in information. EDF recognizes that time constraints apply to these first ten chemicals and thus some types of testing may not be possible, but going forward, EPA needs to use its authority fully and do so in a timeframe that ensures it will have all of the information it needs to conduct risk evaluations.

As EPA moves forward on the first 10 risk evaluations, it should first clearly identify *all* significant information gaps on hazards or exposures. Based on its own regulation, EPA must then use its authority under TSCA § 4(a)(2) to require the development of new information to fill those gaps wherever possible. Information that EPA can generate under TSCA § 4(a)(2) is reasonably available under EPA's own regulation as "information that EPA *** can reasonably generate [and] obtain *** for use in risk evaluations." 40 C.F.R. § 702.33. Thus, EPA should identify such information gaps and then promptly require the conduct of all testing that can be done and still meet the statutory deadlines for the risk evaluations.

TSCA § 4(a)(2) provides that EPA "may, by rule, order, or consent agreement require the development of new information relating to a chemical substance *** if the Administrator determines that the information is necessary *** to perform a risk evaluation under section 6(b)." 15 U.S.C. § 2603(a)(2)(A)(i). Congress provided this additional testing authority allowing EPA to require testing or other data development efforts solely upon a determination "that the information is necessary *** to perform a risk evaluation under section 6(b)." *Id.* In light of deadlines, EPA can and should use its order authority and does not need to make the additional findings required for a rule under TSCA § 4(a)(1).

In places in these scopes, EPA seems to be going out of its way to avoid using its information authorities. For example, in numerous places in these scopes, with respect to exposure, EPA indicates that "[f]or conditions of use where data are limited or not available, [it will] review existing exposure models that may be applicable in estimating exposure levels" (p.43). This language suggests that EPA will simply default to models rather than use its authority to get needed information. In EDF's view, EPA should first use its authorities under TSCA §§ 8 and 4 to fill those information gaps, rather than rely on models to compensate for lack of information. This is not to say that exposure models do not have a role, but they are not a basis for avoiding the obligation to collect information.

Our review of the scopes indicates that there are significant gaps in the information. Where possible EPA needs to fill those gaps. When it is not possible, consistent with TSCA § 26, EPA needs to identify those gaps and characterize the uncertainty in the draft risk evaluations. To cite just one example, in the scope for Methylene Chloride EPA completely fails to mention an information gap earlier identified in the Work Plan. Specifically, the 2014 Work Plan Assessment for Methylene Chloride identified both developmental neurotoxicity and immunotoxicity from chronic exposure as important data gaps, impacting the selection of the point of departure:

> There is uncertainty about chronic exposure impacts on the nervous system function. The nervous system has been well studied and identified as very sensitive for acute effects. However, there is a paucity of data on chronic neurological impacts, especially developmental neurotoxicity. Likewise, there is limited information about immunotoxicity following chronic exposure to DCM. Existing hazard studies are not sufficient for dose response analysis to provide a lower point of departure than existing adverse findings in the liver from chronic exposures."

See Methylene Chloride: Paint Stripping Use, TSCA Work Plan Chemical Risk Assessment at p.115, https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf

C. If EPA already has relevant information, it is reasonably available and EPA should consider it.

The strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." *See, e.g.*, Asbestos literature at p.13. But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation *** is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available, EPA must review it.

In addition, much of this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. First, historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act. Second, the Lautenberg Act greatly increased the requirements companies must meet to assert CBI claims. For example, information only qualifies for protection if the submitter asserts *and* substantiates that it has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c). Thus, even if the information once merited protection, it may no longer be confidential under the standards of TSCA § 14. Third, as a general rule, TSCA § 14(b)(2) provides that health and safety studies and information from health and safety studies are not entitled to confidential treatment, so much of this information may not be confidential under that provision.

To fulfill its duties under TSCA, EPA must review this reasonably available information and identify that which is potentially relevant to the risk evaluations. Where information is relevant, EPA should also consider whether the information meets the strict requirements for nondisclosure under TSCA § 14. If not, EPA should add it to the administrative record for review by the public. Whether or not it meets those requirements, EPA should then determine whether and how to consider the information in evaluating these chemicals. Notably, TSCA § 26(j) requires that, "subject to section 14," EPA "shall make

available to the public *** a list of the studies considered by [EPA] in carrying out each such risk evaluation, along with the results of those studies." 15 U.S.C. § 2625(j).

D. When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information.

In the literature searches, EPA sometimes states that it relied on recent assessments, and then only performed research for dates beyond those assessments. *See, e.g.*, 1,4-Dioxane, Strategy for Conducting Literature Searches for 1,4-Dioxane: Supp. File for the TSCA Scope at p.7, 9-10, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0047. EPA needs to provide a short analysis presenting its review of the prior analysis to ensure it adequately captured and addressed all reasonably available information as of the date of its publication, particularly given the expanded obligations under the Lautenberg Act. If EPA finds it was not adequate, then EPA should broaden its literature search.

III. EPA needs to take additional steps to ensure both the completeness and accuracy of the information it relies upon.

As explained above, EPA should rely on its authorities under TSCA §§ 8 and 4 to obtain all reasonably available information. Those authorities include a number of measures to ensure the accuracy and completeness of the data relied upon. To the extent EPA relies on voluntarily submitted information, EPA needs to take additional steps to ensure the accuracy and completeness of the information. Otherwise, EPA will violate TSCA § 26 by failing to make decisions "in a manner consistent with the best available science." 15 U.S.C. § 2625(h)

A. EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals.

EPA has requested in each of the scopes that industry and other stakeholders provide information. While this voluntary request was a reasonable first step towards obtaining the necessary information, EPA has failed to provide any account for how this voluntary approach to collecting information will result in EPA obtaining all "reasonably available" information as EPA has defined that term. There are several obvious problems and limitations with this voluntary approach which EPA has not even acknowledged, much less addressed.

First, a voluntary call is much less likely to produce all of the necessary information than rules mandating that affected parties provide the requested information. If manufacturers and processors are legally required to provide the information, that legal obligation provides a strong incentive for them to collect and submit all relevant information. Absent that incentive, some companies may choose to focus time and attention on other matters. Indeed, the burdens (whether one considers them heavy or light) of collecting and submitting information counsel in favor of issuing mandatory rules. *If* the process of

collecting and submitting the information is not onerous or difficult, then using rules to require the submission of the information will do little if any harm to the regulated industry, and use of rules will ensure EPA has a complete picture and increase credibility. Alternatively, to the extent that the process is onerous or difficult, it is even more important that EPA *require* the submission of the information, because otherwise those burdens will likely discourage stakeholders with relevant information from collecting and submitting the information.

Second, EPA has provided no empirical evidence establishing that this voluntary approach will result in EPA obtaining all "reasonably available" information. Unless EPA has some empirical basis for stating that the voluntary approach will allow EPA to obtain all reasonably available information that it can obtain under its legal authorities, EPA must rely on its existing authorities to obtain a complete set of information.

Indeed, EPA's prior experience with voluntary reporting provides strong evidence that a voluntary approach is unlikely to provide complete and accurate data. For example, an EPA advisory committee called for the development of nanomaterial reporting rules in 2005, but EPA instead spent several years developing and carrying out a voluntary reporting program, the Nanoscale Materials Stewardship Program (NMSP). This voluntary reporting program produced minimal information as revealed by EPA's 2009 interim report on the NMSP. Nanoscale Materials Stewardship Program, Interim Report, OPPT (Jan. 2009), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0003. "[I]n the report EPA estimated that companies provided information on only about 10 percent of the chemical substances manufactured at the nanoscale that may be commercially available in 2009." 80 Fed. Reg. 18,330, 18,334 (April 6, 2015). In 2017, over a decade after the data need was identified, EPA finally finalized a § 8(a) reporting rule to acquire the data. 82 Fed. Reg. 3641 (Jan. 12, 2017). Given the past failures of voluntary approaches, EPA should not rely on them here.

Third, manufacturers and processors of these chemicals have a vested interest in EPA finding that the chemicals do not present an unreasonable risk. A no-unreasonable-risk finding reduces the likelihood of government regulation, including potential restrictions on risky chemicals, and it may reduce any stigma they may otherwise face in the marketplace. The financial costs of regulation may ultimately be very high for some specific firms and individuals, and even if not, many firms and individuals may *believe* that the costs of regulation will be high. These companies have a "financial interest" in the outcome of these proceedings, and they are not impartial. *See, e.g.*, 28 U.S.C. § 455(b)(4) (requiring Judges to disqualify themselves in proceedings where they have a financial interest). Because of this reality and appearance of partiality, relying solely on voluntary measures decreases the credibility of these risk evaluations.

Relying solely on voluntary presentation of information raises the concern that the companies or trade associations may present an incomplete or skewed picture. Companies and trade associations may choose to "cherry pick" information and provide only the information that paints their chemicals in favorable light. They may provide only summaries of information that reflect conscious and subconscious judgment calls that result in unduly favorable conclusions; and without access to the full information neither EPA nor the public can independently assess such conclusions. They may choose

not to review records robustly when the review may disclose unfavorable information. They may seek to put their best foot forward and describe the ideal scenario of use and safety measures. Or, if they have unfavorable information, they may choose not to provide any information at all and simply not participate in these proceedings.

To be sure, members of the regulated community are crucial sources of information about their chemicals' uses, hazards, and exposures, but EPA cannot simply assume that they will voluntarily disclose unfavorable or complete information about their practices and products. *See* THE FEDERALIST NO. 51 (James Madison) ("If men were angels, no government would be necessary. *** [E]xperience has taught mankind the necessity of auxiliary precautions."); *Williams v. Pennsylvania*, 136 S. Ct. 1899, 1905-06 (2016) ("Bias is easy to attribute to others and difficult to discern in oneself. *** This objective risk of bias is reflected in the due process maxim that 'no man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome.'"). Here, manufacturers and processors obviously have an interest in the outcome, and EPA must craft its procedures and approaches with that reality in mind. Requiring the submission of information is the safest approach to ensuring that these parties provide all relevant information, and that is in turn crucial to establishing and demonstrating the credibility of this process.

If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information. First, EPA can require that certain information and underlying information be provided in full, which ensures completeness. In addition, a § 8(d) rule requires that people engage in an adequate search of records. 40 C.F.R. § 716.25. Second, submitters must file certification statements by authorized officials that certify that the submitted information has been submitted in compliance with the requirements of this process. *See, e.g.*, 40 C.F.R. § 711.15(b)(1). Third, submitters often must retain records of required submissions for a period of five years, and the retention of records can help encourage accurate reporting since those records would be available should a submission latter be investigated. *See, e.g.*, 40 C.F.R. § 711.25. None of these features apply to the voluntary requests for information EPA has indicated it is relying on.

In addition, as EDF has explained in prior comments, there are numerous reasons that it is important that the public have access to full studies and the underlying information, not simply robust or other study summaries. *See, e.g.*, EDF Comments on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act, Comment at p.37, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074. Without access to full studies, the public will be challenged or unable to assess and comment on the quality of the studies used by the agency. *Id.* EDF reincorporates and reiterates the numerous points made in support of public access to the full studies here. *Id.* These points also support the importance of EPA obtaining the full studies.

B. For voluntary submissions, EPA should take additional steps to ensure completeness and accuracy and to vet information based on underlying data.

To the extent it relies on voluntary submissions, EPA can and should take additional steps to better ensure that the voluntary information it receives is accurate and complete. EPA would need to develop a far more rigorous and structured process than it currently has. For example, EPA's submission process does not appear to require anyone to certify that the information in their comments is accurate or complete to the best of their knowledge. EPA should consider approaches for vetting statements and assertions, particularly when made by entities with a financial interest in the outcome of these risk evaluations.

EPA should also request that submitters always provide full studies, as well as underlying data whenever reasonably available or obtainable. Setting aside concerns about partiality, EPA needs the underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular submission.

In addition, EPA should seek input directly from workers for manufacturers and processors, providing them an easy method to submit information on workplace practices and conditions independently from management. EPA needs to take steps to allow workers to provide input in a manner that reduces the risks of any potential retaliation from management.

To give a few specific examples from the scopes:

In the Perchloroethylene scope (also known as tetrachloroethylene or PCE), EPA cites the Vinyl Institute's comments for the fact it can be a residual or byproduct in the manufacture of other chemicals. *See* Perchloroethylene, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0732 (citing comment at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0013). That comment, in turn, contains a table claiming to summarize the approximate concentrations of Perchloroethylene in light and heavy end liquid intermediate streams yielded in the EDC/VCM process for manufacturing each of four chlorinated organic substances. The comment states that there is no residual Perchloroethylene in light liquid ends and 1.1% by typical weight in heavy liquid ends. But the comment does not provide or cite any underlying data supporting these findings. When commenters provide summary statements along these lines, EPA should give them little weight unless it also receives the underlying data to ensure that the reported results or conclusions drawn accurately reflect real-world conditions and to assess the level of certainty and scope of applicability that EPA can attribute to the results or conclusions. This point holds for all of the percentages set forth in that table, including those for the other three products.

Similar concerns arise for many of the other scopes. For example, in the Carbon Tetrachloride scope, EPA states that: "there are public comments, EPA-HQ-OPPT-2016-0733-0005 [3M] and EPA-HQ-OPPT-2016-0733-0017 [ACC], stating that carbon tetrachloride may be present in a limited number of industrial products with chlorinated ingredients at a concentration of less than 0.003% by weight." Carbon Tetrachloride, Scope at p.20, Docket ID: EPA-HQ-OPPT-2016-0733. But upon examining those

comments, they do not provide any of the underlying data or enough information to assess accuracy of the statement or the level of uncertainty that should apply to the results. The ACC comment is particularly difficult to assess. It involves multiple levels of hearsay, with ACC reporting statements that companies reported to it. Some of those companies acknowledge they are also relying on hearsay from suppliers and have not taken steps to confirm these concentrations. Those suppliers might also be relying on hearsay; it is simply not clear what the bases are for some of these values. Hearsay is, of course, particularly problematic when the statement serves the interest of the person submitting the evidence. *See, e.g.*, FED. R. EVID. P. 804(b)(5) (exception for statements against interest). As such, these concentrations arguably provide at best a "lower bound" estimate; they are not sufficient in terms of establishing that the actual concentrations are not higher. While no formal hearsay rule applies to these administrative proceedings and the hearsay evidentiary rule generally has limited applicability to technical studies and business records, it is relevant to the weight EPA should give these reported values given these circumstances. ACC does not disclose the companies providing the information, making it impossible for EPA to independently address these kinds of concerns. In addition, ACC's comment often fails to provide any clarity or detail as to how the concentrations were measured or assessed, much less provide the data underlying these claimed concentrations. The ACC comment asserts concentrations for 1,4-Dioxane, Pigment Violet 29, N-Methylpyrrolidone (NMP), Methylene Chloride (DCM), Carbon Tetrachloride, and HBCD, but for most of these concentrations, it is impossible for EPA or the public to assess whether they are accurate. For some of these concentrations, the comment states that Safety Data Sheets and Technical Data Sheets are provided with the comments, but EDF did not find any attachments with the comment containing those materials. In sum, EPA needs to scrutinize these voluntary submissions carefully and ensure access to the underlying information, which is necessary to assess the accuracy of the statements therein.

In the asbestos scoping document, EPA acknowledged that the analysis of the Chlor-Alkali industry was "primarily based on information provided by either the chlor-alkali industry or [the American Chemistry Council] and is meant to represent typical practices." *See* Asbestos, Scope at p.54, Docket ID: EPA-HQ-OPPT-2016-0736. EPA correctly recognized that EPA should "further evaluate how representative the processes witnessed at these two facilities are of processes at other plants." *Id.* at 23. EPA should take measures to ensure that its process will in fact accurately assess the full range of existing practices, relying on independent data where possible. Where independent data are unavailable, EPA should reach out to workers directly to better determine actual practices. Even when companies have good practices on paper, those practices may not be the reality on the ground.

EPA also needs to carefully scrutinize statements to ensure it correctly interprets them.

IV. These scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations.

Broadly viewed, the scopes do not meet several of the statutory requirements of TSCA. TSCA § 6(b)(4)(D) requires that EPA "shall, not later than 6 months after the initiation of a risk evaluation,

publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D). These scopes do not fully satisfy these requirements. Some aspects are plainly illegal under *any* interpretation of the statute, for the reasons given above, such as the statement that "EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11).[1] But many other aspects, while problematic, can be resolved by EPA in the next step: its development of problem formulations.

It is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. EDF believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified. With respect to susceptible populations, EPA should consider workers and, in most cases, pregnant women and children, to be potentially exposed or susceptible subpopulations. We identify below a number of specific examples where EPA's scopes are unclear and merit further study.

A. 1,4-Dioxane

EPA states: "EPA evaluated the weight of the evidence for cancer in humans and animals and concluded that 1,4-dioxane is 'likely to be carcinogenic to humans' based on evidence of carcinogenicity in several 2-year bioassays." 1,4-Dioxane, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0723. However, certain language in this section suggests that EPA may not include cancer as a hazard endpoint in the risk evaluation.

Indeed, EPA almost seems to suggest that inconclusive evidence regarding the "mode of action by which 1,4-dioxane produces liver, nasal, peritoneal (mesotheliomas) and mammary gland tumors" might form a basis for disregarding the evidence of such hazards. *Id.* at 35. As a general matter, EPA should not exclude observed hazards simply because the underlying MOA is not fully delineated or understood, doing so would significantly and inappropriately jeopardize the robustness and health-protections of the risk evaluation. If there is evidence of hazard, EPA should include it in the risk evaluation, even if the precise mode of action is not yet understood.

[1] As explained above, EPA puts too much weight on a floor statement from a single Senator, David Vitter. But even Senator Vitter stated that EPA must consider all conditions of use identified in the scope. *See* 114 Cong. Rec. S3520 (daily ed. June 7, 2016) (statement of Sen. Vitter). Despite that statement, the scoping documents all state that "during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11). Thus, EPA is inconsistent in how much weight it gives to Senator Vitter's statements, and EPA's current interpretation appears to contradict the views expressed throughout the legislative history by every single legislator. If EPA excluded uses identified in the scope, such as uses in the chlor-alkali industry (e.g., pp.20, 23-24), then EPA will be acting contrary to Senator Vitter's statement.

B. Perchloroethylene

The scope for Perchloroethylene states that "EPA expects to consider hazards identified in the recent assessment by the EPA Integrated Risk Information System (IRIS) Program: neurotoxicity, kidney toxicity, liver toxicity, developmental and reproductive toxicity and cancer. Support for an association with immune and blood effects was less well characterized." Perchloroethylene, Scope at p.11, Docket ID: EPA-HQ-OPPT-2016-0732. It is unclear from the scope whether EPA intends to include immune and blood effects in particular.

C. Trichloroethylene (TCE)

In the scope for TCE, EPA suggests that TCE's use as a spot remover will not be analyzed because it was previously analyzed in a risk evaluation. TCE, Scope at p.25, Docket ID: EPA-HQ-OPPT-2016-0737. That approach may be reasonable if EPA finalizes its proposed ban on this use of TCE to address those risks, as discussed more below. But that approach only applies to those spot remover uses that have previously been analyzed, specifically commercial dry cleaning facilities. This risk evaluation needs to consider TCE's use as a consumer spot remover. Those uses have not been analyzed in-depth, and the 2014 work plan assessment recognized that some such products may contain TCE as a main ingredient. *See* Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses, TSCA Work Plan Chemical Risk Assessment at p.52, https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

D. N-Methylpyrrolidone (NMP)

The NMP scope has numerous inconsistencies with respect to its identification of the endpoints to be assessed. EPA begins by acknowledging that a "number of human health hazards have been identified for NMP including adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems." N-Methylpyrrolidone, Scope at p.36, Docket ID: EPA-HQ-OPPT-2016-0743. EPA also states that: "EPA expects to consider all potential hazards associated with NMP." *Id.* EDF completely agrees with that approach. However, the description under section 2.42 Human Health Hazards indicates that EPA intends to focus on a narrower set of hazards (acute toxicity and reproductive/developmental toxicity), and provides no justification or even explanation for excluding some of the hazards that it previously identified.

E. Potentially exposed or susceptible subpopulations

EPA also does not identify pregnant women, women of childbearing age, or the developing fetus as potential exposed or susceptible subpopulations for either N-Methylpyrrolidone (NMP) [NMP, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0743] or TCE [TCE, Scope at pp.37-38, Docket ID: EPA-HQ-OPPT-2016-0737], despite the fact that EPA's previous risk assessments on these two chemicals identify women of childbearing age and the developing fetus as a primary susceptible population (in addition to workers). EPA's failure to identify these populations in the scopes is both contrary to law and an abuse of discretion. TSCA § 3(12) defines "potentially exposed or susceptible subpopulation" to include "a

group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance *** , such as infants, children [or] pregnant women." 15 US.C. § 2602(12). Here, EPA has previously found that "women of childbearing age" are at greater risk of adverse health effects from these chemicals. 82 Fed. Reg. 7432, 7434 (Jan. 19, 2017); 82 Fed. Reg. 7464, 7467 (Jan. 19, 2017).

Furthermore, TSCA requires that EPA identify "the potentially exposed or susceptible subpopulations the Administrator expects to consider" in the scopes. 15 US.C. § 2605(b)(4)(D). While EPA has considered those at greater risk due to *increased exposure* in the scopes to some extent, the agency appears to defer the process of identifying populations with *greater susceptibility* to the problem formulation or risk evaluation stage: "In developing the hazard assessment, EPA will also evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s)." *See, e.g.*, NMP, Scope at pp.36-37, Docket ID: EPA-HQ-OPPT-2016-0743; 1,4-Dioxane, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0723.

V. EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures.

The scoping documents generally acknowledge the need to analyze activities related to a chemical's distribution, but EPA will need to analyze these exposures more robustly than the scopes currently reflect. *See, e.g.*, 1,4-Dioxane, Scope at p.22, Docket ID: Docket ID: EPA-HQ-OPPT-2016-0723.

The scoping documents give little, if any, attention to potential releases and exposures resulting from accidental releases. EDF does not suggest that EPA needs to consider every possible scenario, but the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks. For example, as and after Hurricane Harvey passed through Houston, over 40 sites released toxic chemicals into the environment. *See, e.g.*, More Than 40 Sites Released Hazardous Pollutants Because of Hurricane Harvey, https://www.nytimes.com/interactive/2017/09/08/us/houston-hurricane-harvey-harzardous-chemicals.html?_r=0. Given the *known* accidental releases, the huge number of petrochemical plants and refineries in the Houston area, and the likelihood that flooding there may become more common in light of climate change, such events are clearly reasonably foreseen and hence EPA needs to give more consideration to the potential for accidental releases.

VI. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures.

Language used in the scopes suggests that EPA may inaccurately assume that people comply with all warning labels and always use personal protective equipment (PPE). EDF strongly urges EPA to consider real-world exposures reflecting the reality of the sometimes low-compliance with or non-existence of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by

either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). And absent empirical evidence establishing the extent to which people are using these measures, EPA should assume that they may not be. Indeed, EPA's need for accurate information about actual compliance is another reason to rely on its authorities under TSCA § 8 to mandate that manufacturers and processors provide that information. In addition, it bears noting that reliance on PPE as a primary measure to protect workers is counter to OSHA's Industrial Hygiene Hierarchy of Controls (HOC), a long-standing principle that prioritizes measures to eliminate or reduce the presence of a hazard in occupational settings (e.g., substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves, such as through reliance on PPE and warning labels. The HOC exemplifies the best available science for creating safe, healthful workplace environments.

As an example of a problematic reference to PPE in the scopes, in the asbestos scope, EPA stated that "[d]ermal exposure is unlikely due to glove use in the workplace." Asbestos, Scope at p.37, Docket ID: EPA-HQ-OPPT-2016-0736. But EPA cites no evidence supporting this assumption. While gloves may be used in many workplaces, EPA needs to provide evidence of the extent of such use. Among other things, EPA correctly noted earlier that "certain conditions of use, such as a mechanic changing asbestos-containing brakes, may also result in dermal exposure." *Id.* at 35. Is there any evidence that all or even most mechanics wear gloves when changing brakes? Indeed, EPA should identify mechanics as a relevant potentially exposed or susceptible subpopulation based on their exposure to brakes.

In comments EDF has submitted in these dockets, EDF previously commented on the serious limitations of labeling and PPE, as well as the importance of adherence to the hierarchy of controls to limit workplace exposures. *See, e.g.*, EDF comments at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0046, March 15, 2017; and at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052, November 21, 2016. EDF reincorporates and reiterates the points made in those comments here.

VII. EPA's decision not to examine uses addressed by its planned § 6(a) rules governing certain uses of TCE, DCM, and NMP is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses.

For Trichloroethylene (TCE), Methylene Chloride (DCM), and N-Methylpyrrolidone (NMP), EPA states that conditions of use previously examined will not be re-evaluated. TCE, Scope at p.9, Docket ID: EPA-HQ-OPPT-2016-0737; DCM, Scope at p.29, Docket ID: EPA-HQ-OPPT-2016-0742 ("This includes uses assessed in the U.S. EPA (2014a) risk assessment and therefore those uses are out of scope for the risk evaluation."); NMP, Scope at pp.20, 28, Docket ID: EPA-HQ-OPPT-2016-0743 ("This includes uses assessed in the previous EPA risk assessment (U.S. EPA, 2015) and therefore those uses are out of scope for the risk evaluation."). EPA has previously found these uses even by themselves present unreasonable risks to human health. In addition, these uses have the potential to increase the total

exposure of people to these chemicals. As a result, EPA can only reasonably exclude these uses if it finalizes the proposed rules to ban these uses. EDF strongly supports those bans for the reasons it articulated in its prior comments.

If EPA does not finalize these bans, then excluding these uses is both contrary to law and arbitrary and capricious. By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses *unless* EPA has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals.

* * * * *

EDF appreciates the opportunity to provide comments and EPA's consideration of them.

Environmental Defense Fund Comments on

Ten Scopes under the Toxic Substances Control Act

Docket IDs: EPA-HQ-OPPT-2016-0725 (Pigment Violet 29), EPA-HQ-OPPT-2016-0723 (1-4, Dioxane), EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene), EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride), EPA-HQ-OPPT-2016-0735 (HBCD), EPA-HQ-OPPT-2016-0736 (Asbestos), EPA-HQ-OPPT-2016-0737 (Trichloroethylene), EPA-HQ-OPPT-2016-0741 (1-Bromopropane), EPA-HQ-OPPT-2016-0742 (Methylene Chloride), and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone)

Submitted Tuesday September 19, 2017

The Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the scopes for the risk evaluations for the first ten chemicals being evaluated under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

In addition to specific comments on each chemical, EDF is providing broad comments addressing the scopes of risk evaluations for the first 10 chemicals as well as others in the future. While our comments are broadly applicable to all of the scope documents, we include examples from specific scopes to illustrate flaws and limitations.

As explained below, these scopes deviate from certain requirements of the law and in places are too unclear and vague or ambiguous to allow us to provide definitive comments. EDF recognizes that EPA was working under tight deadlines in producing these scopes – a problem it further exacerbated by EPA's decision to make major, late changes to the risk evaluation rule. EPA should take advantage of the upcoming problem formulation stage to address the many problems we identify below, and to more clearly and transparently explain its plans for these risk evaluations.

Before discussing the merits of the scoping documents, EDF provides the following clarification about its citation approach. Each scoping document contains largely identical, boilerplate language providing the agency's overall legal approach to "conditions of use" as well as its approaches on some other issues. Indeed, each document includes the same typos or misquotes of the underlying law. For ease of reference and to reduce excessive citations, EDF quotes from the asbestos scoping document and provides simply the page number when addressing these broader legal problems that are present in each scoping document. These comments equally apply to all scoping documents since they all contain

this same language; the only difference is page number. When EDF is specifically quoting another scoping document, we provide a citation clarifying that point.

Contents:

I. TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use.

EPA's scoping documents (pp.11-13) state that EPA has determined that "certain activities may not generally be considered to be conditions of use" (p.11) and also that EPA may "exclude certain activities that EPA has determined to be conditions of use" (p.12). EPA's approach asserts that EPA is allowed to ignore numerous circumstances falling within the statutory definition of "conditions of use" and is contrary to law. For the current set of chemicals under review, EPA may well be ignoring circumstances leading to ongoing exposures, and as a result, will fail to evaluate the risks the chemicals actually pose to human health and the environment.

TSCA's language and structure unambiguously foreclose EPA's interpretation. EPA's decision to disregard certain uses and exposures is also "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to consider "factors which Congress has not intended it to consider [and] entirely fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, as the scoping documents themselves reveal, this approach leads to irrational and arbitrary applications. Instead, EPA should be guided by the statutory language and consider all of those circumstances falling within the definition of "conditions of use." EPA should evaluate all of the circumstances revealed by the evidence of use and exposure, not ignore evidence because of self-imposed blinders.

A. The plain text, overall structure, purpose, and legislative history of TSCA indicate that EPA has to determine whether a chemical substance presents an unreasonable risk comprehensively, under all of its conditions of use.

i) *The plain text requires EPA to consider all conditions of use.*

Statutory interpretation should begin, as always, with the language of the statute. The plain language of both the risk evaluation provision and the definition of conditions of use support the interpretation that EPA must consider all circumstances falling within the statutory definition of "conditions of use." The main risk evaluation provision, TSCA § 6(b)(4)(A), directs that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). Inserting the statutory definition of conditions of use, this provision provides that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* §§ 2605(b)(4)(A), 2602(4). Thus, EPA has to analyze the risks of a substance under the circumstances described in the definition of "conditions of use," and no qualifying language allows EPA to exclude circumstances within that definition. The clause "as determined by the Administrator" calls for a factual finding or determination to be made by EPA. The relevant dictionary definition of "determine" is to "ascertain or establish exactly, typically as a result of research or calculation." OXFORD

AMERICAN DICTIONARY 474 (3d ed. 2010). While EPA may exercise reasonable judgment when interpreting "reasonably foreseen," nothing in this language grants EPA discretion to *ignore* factual circumstances that fall within the definition of "conditions of use." Indeed, statutes often direct agencies "to determine" things or make "determinations," and it is understood that the agency must make the finding required by the statutory language.

EPA's position that it can ignore known and foreseeable uses violates the text of the law. In the scoping documents, EPA asserts that it may ignore "legacy uses" and "associated disposals," impurities, alleged "de minimis" exposures, intermediates, conditions of use within closed systems, and conditions of use that have been analyzed by another regulatory agency (p.12). But "conditions of use" expressly includes "the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen to be to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). And every one of those circumstances is a "known" or "reasonably foreseen" "manufacture", "process[ing]," "use," or "disposal of" a chemical substance. Congress expressly chose to define "conditions of use" broadly to include not only "intended," but also "known" or "reasonably foreseen" manufacture, processing, distribution, use, and disposal. 15 U.S.C. § 2602(4). Disregarding chemical substances present as impurities or byproducts in the scoping documents, for example, because they are not "intended" essentially reads the other two scenarios out of the statute. Similarly, all the other identified conditions of use are also "intended, known, or reasonably foreseen." For example, EPA's scope suggests that 90% of the domestic production of Pigment Violet 29 "is processed as a site-limited intermediate." Pigment Violet 29, Scope at p.19, Docket ID: EPA-HQ-OPPT-2016-0725. It would absurd to ignore these intermediate uses when analyzing this chemical; doing so will lead to a truncated and incomplete analysis. Similarly the decision to exclude 1,4-dioxane's presence in numerous consumer, commercial, and industrial products as a byproduct of ethoxylation is entirely inappropriate, and will result in deficient and erroneous evaluation and determination of the chemical substance's risks. The same points can be made for many of the other chemicals used as intermediates or present as byproducts of chemical or product manufacture.

In contrast to the correct interpretation, EPA's new interpretation finds no support in the text. In the final risk evaluation rule (82 Fed. Reg. 33,726, 33,729 (July 20, 2017)), the only statutory textual basis for EPA's theory appears to be the "expects to consider" clause in the scope provision, TSCA § 6(b)(4)(D), requiring EPA to "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator *expects to consider*." 15 U.S.C. § 2605(b)(4)(D). But "expects to consider" does not mean "chooses to consider" or "prefers to consider." It is not the language of discretion; it is temporal language of anticipation or prediction. The dictionary definition of "to expect" is to "regard (something) as likely to happen." OXFORD AMERICAN DICTIONARY 609 (3d ed. 2010). This language indicates that, in the scope, EPA should describe what it anticipates studying, but it does not state that EPA has discretion to choose to ignore intended, known, or reasonably foreseen uses, hazards, or exposures. Moreover, the provision dictating what EPA must consider during a risk evaluation does not limit EPA's analysis to conditions of use identified in the scope. 15 U.S.C. § 2605(b)(4)(F). Indeed, EPA must consider all such conditions to fulfill its requirement that EPA account for the "likely duration, intensity, frequency, and

number of exposures under the conditions, where relevant." 15 U.S.C. 2605(b)(4)(F)(iv). Thus, the statutory language does not support EPA's assertion of discretion, including EPA's decision to limit its analyses to those factors identified in each scope. For example, under the rule of the last antecedent, the phrase "the Administrator expects to consider" does not even *modify* "conditions of use" or "hazards" or "exposures." Notably, EPA has so little regard for the statutory language that it repeatedly misquotes this language in significant ways.

Textually, EPA's argument also directly conflicts with TSCA § 26(k). 15 U.S.C. § 2625(k). TSCA § 26(k) requires EPA to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." *Id.* Notably, this requirement does not include *any* conditional phrase that modifies "conditions of use." And Congress included this provision to ensure that EPA could not ignore "reasonably available" "information relating to a chemical substance or mixture"; the purpose of this provision is to compel EPA to consider all reasonably available information. It would undermine this directive if EPA chooses to arbitrarily ignore certain uses and related exposures.

ii) *TSCA's overall structure requires EPA to consider all of the conditions of use.*

TSCA provisions direct EPA to prepare risk evaluations and the related findings for "chemical substances," *as a whole*, not for specific or limited conditions of use of those substances. For example, the risk management provision expressly requires EPA to address risks when the risks arise from combined exposure. TSCA § 6(a) provides that: "If [EPA] determines in accordance with [the risk evaluation provision] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, *or that any combination of such activities*, presents an unreasonable risk of injury to health or the environment," then EPA must issue a risk management rule. 15 U.S.C. § 2605(a); *see also* 15 U.S.C. § 2608(a) (using same language in provision governing requests to other federal agencies to address risks). Thus, if "any combination" of conditions of use presents an unreasonable risk, EPA must issue a risk management rule. But EPA must analyze *all* of these activities to assess whether *any combination* presents a risk.

When describing the end of a risk evaluation, TSCA requires EPA to make a finding about the "chemical substance" with no reference to conditions of use. *See, e.g.*, 15 U.S.C. § 2605(c)(1), (*i*) ("If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A)," then EPA must issue a regulation to address the unreasonable risk.). The absence of any reference to conditions of use makes it clear that EPA must make a finding for a chemical substance as a whole, not one limited to certain conditions of use. Notably, in the final prioritization rule, EPA correctly reasoned that this type of language indicated that EPA had to consider *all* uses in prioritization. *See* 82 Fed. Reg. 33,753, 33,755 (July 20, 2017) ("The statute directs EPA to make prioritization determinations on a 'chemical substance' or 'substance,' not on 'uses,' *see, e.g.*, 15 U.S.C. §§ 2605(b)(1)(A)-(C), and in most cases, without reference to 'the conditions of use.'"). This reasoning equally applies to risk evaluations.

iii) *TSCA's purpose, as well as basic logical reasoning and the best available science, require EPA to consider all conditions of use to assess a chemical substance as a whole.*

The purpose of the risk evaluation is to analyze the risks of a substance based on an assessment of its hazards and exposures. Ignoring potential exposures at the outset undermines that purpose. And science and logic do not support EPA's exceptions. For example, EPA states that it may disregard so-called "de minimis" exposures from conditions of use that occur in a closed system or use as an intermediate (p.12). But intermediates are often not completely consumed in chemical reactions and may remain as a residual in final reaction products. *See, e.g.*, California Department of Toxic Substances Control, Spray Polyurethane Foam Systems Containing Unreacted Methylene Diphenyl Diisocyanates, http://www.dtsc.ca.gov/SCP/Spray_Polyurethane_Foam.cfm (last visited Sept. 18, 2017). So the presumption that intermediates lead to a "de minimis" exposure is often contrary to the scientific evidence. In addition, intermediates must still be manufactured as well as typically being stored, transferred, or distributed, all of which are activities that can lead to exposures – including to workers, whom TSCA expressly identifies as a "potential exposed or susceptible subpopulation." Similarly, unintended impurities or contaminants can nonetheless lead to exposures and hence risks to human health or the environment, the significance of which needs to be determined in conducting a risk evaluation. *See infra* at pp.10-11 (discussing 1,4-dioxane). Ignoring them at the outset is contrary to the purpose of TSCA and risk evaluations, as well as the law's requirement that EPA rely on the best available science.

To be sure, EDF generally agrees with EPA's statement that "all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk." 82 Fed. Reg. at 33,734. Legally, EPA may be able to provide a concise and scientifically valid finding that a particular condition of use—such as the use phase of a chemical used as an intermediate—leads to little or no exposure and risk in a particular case, based on less than an in-depth analysis. And TSCA does not require a quantitative evaluation when a qualitative evaluation is determined and documented to be appropriate. But TSCA does not authorize EPA to simply "exclude" conditions of use at the outset as a matter of legal discretion. Furthermore, EPA must provide a scientific, data-backed rationale for why it decides a less extensive evaluation is sufficient, and cannot merely rely on a lack of data for such a decision.

EPA is imposing blinders on its analysis by asserting its authority to refuse to look at certain conditions of use, including known uses and disposals, and the result is that EPA is overlooking exposures in the real world. This approach is both contrary to law and arbitrary and capricious, as explained *infra* at Part I.D.

iv) *The legislative history does not justify or even lend support to EPA's approach.*

To justify its new position, EPA has emphasized the "legislative history" (p.11). But the legislative history, read as a whole, does not support EPA's approach. In the risk evaluation rule, EPA claims that the "legislative history of the amended TSCA *** explicitly states that the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation." 40 Fed. Reg. at 33,728 (citing 114 Cong. Rec. S3519-20 (daily ed. June 7, 2016) (statement of Sen. Vitter)). EPA relies on a floor

statement from a single Senator, which is one of the least illuminating forms of legislative history. EPA ignores that the rest of the legislative history reveals that other Senators thought that the statutory language would require EPA to consider all conditions of use in risk evaluations under the Lautenberg Act. Four principal Democratic negotiators of the legislation submitted a statement to the record that: "[t]he definition of 'conditions of use' described above plainly covers all uses of a chemical substance." 114 Cong. Rec. S3516 (daily ed. June 7, 2016). Similarly, when explaining why the bill expressly "grandfathered" in prior risk assessments (such as for Methylene Chloride), these negotiators explained that the provision was necessary because those "risk assessments for these chemicals were not conducted across all conditions of use." *Id.* at S3519. This explanation clearly reflects that *future* risk evaluations under TSCA would have to be conducted "across all conditions of use."

Unlike the text and structure of TSCA, the legislative history is somewhat ambiguous at points, although, if anything, it supports the position that EPA must consider "all conditions of use" since more Senators expressed that view and they did so in a formal statement.

B. Conditions of use expressly include certain so-called legacy uses and associated disposals.

In each of the scopes EPA stated that it *will* exclude so-called "legacy uses" and "associated disposal," (p.12) and EPA appears to rely on its reasoning from the risk evaluation rule. 82 Fed. Reg. at 33,729-30. EPA has asserted that no statutory text addresses this issue, and EPA stated that the use of the phrase "to be" in the definition of "conditions of use" implies a prospective application. 82 Fed. Reg. at 33,730; *see* 15 U.S.C. § 2602(4) (defining conditions of use to "mean[] the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen *to be* manufactured, processed, distributed in commerce, used, or disposed of") (emphasis added). EPA also (inaccurately) asserted that it did "not have an effective tool to address risks found to arise from uses in consumer settings if there" is no on-going manufacture, processing, or distribution. 82 Fed. Reg. at 33,730. But none of this reasoning survives scrutiny.

EPA's argument based on tense clearly does not apply to the legacy uses and associated disposals. If a chemical substance is present in a product or material that an industrial, commercial, or residential consumer is still using, then the substance is known "to be" used in that circumstance. Similarly, if a substance has not been disposed of yet, its disposal is in the future and reasonably foreseeable. As a result, these "legacy uses" and "associated disposal[s]" fall squarely within TSCA's definition of "conditions of use," which includes the "circumstances *** under which a chemical substance is *** known *** to be *** used, or disposed of." 15 U.S.C. § 2602(4). EPA has presented no textual basis for treating the first three participles in the list in this definition (manufactured, processed, and distributed in commerce) differently than the last two participles (used and disposed of).

EPA's theory that § 6 focuses on the "continuing flow of chemical substances" in "their lifecycles" (p.12) completely ignores that the use and disposal of a chemical is *part* of the lifecycle of a chemical, as defined by Congress in TSCA. Indeed, chemicals that are still in use are still "distributed in commerce" as that term is defined in TSCA. 15 U.S.C. § 2602(5). In the final risk evaluation rule, EPA stated that it

"believes the statute is better interpreted to focus on the prospective flow of the chemical substance," 80 Fed. Reg. at 33,730, but Congress expressly covered substances *after* their introduction into commerce as well.

EPA also justified its decision to ignore legacy uses by claiming it lacks tools to address risks from uses in consumer settings if there is no on-going commercial manufacture, processing, or distribution. 80 Fed. Reg. at 33,730. But TSCA § 6(a) expressly provides EPA with authorities that could manage some of these risks, even if it does not provide as broad authority as it does over manufacturers and processors. *See* 15 U.S.C. § 2605(a). For example, at risk management, EPA may impose "[a] requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture." *Id.* § 2605(a)(5). For example, EPA could ban the sale or future use of products containing a chemical even if that chemical is no longer in production in the United States, or EPA could require that such items be labeled. EPA may also impose "[a] requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or *by any other person* who uses, or disposes of, it for commercial purposes." *Id.* § 2605(a)(6)(A) (emphasis added).

In any event, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Indeed, in order to assess real-world risks of a chemical using the best available science, EPA needs to consider even those exposures over which it has limited or shared control. This approach is particularly appropriate given TSCA § 9's referral provisions.

C. The text and overall structure of TSCA makes it clear that EPA has to analyze uses, even if they have been assessed by another agency or are within another agency's jurisdiction.

EPA also stated that it may "exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risk" (p.12). But EPA provides no textual basis for ignoring those uses, which are often "circumstances *** under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Nothing in the risk evaluation provision or definition of conditions of use authorizes EPA to ignore conditions of use because of other agencies' jurisdiction over chemical substances. And several other provisions of TSCA indicate that Congress intended for EPA to consider such exposures, except to the extent Congress explicitly provided otherwise.

First, TSCA § 9(a) provides a detailed procedural mechanism for EPA under certain circumstances to request for another federal agency to address an unreasonable risk arising from a chemical substance that EPA has identified. 15 U.S.C. § 2608(a). This request then triggers a number of duties for both EPA and the other agency, requiring one of the two agencies to take action to address the risk. Thus Congress intended for EPA to prepare risk evaluations analyzing uses that might be addressed by another agency, and Congress created a substantive and procedural mechanism to resolve overlapping jurisdiction only *after* completing the risk evaluation. If EPA could just ignore risks arising from

conditions of use that fall within other agencies' jurisdiction, or if Congress meant for EPA to defer to those agencies' current regulatory approach to those chemicals at the outset before conducting a risk evaluation, then EPA might never make the finding that triggers the § 9(a) process. Here again, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Given that Congress expressly addressed the issue of overlapping regulatory jurisdictions in TSCA § 9, EPA cannot avoid those procedures by simply ignoring uses that fall within another agency's jurisdiction. Furthermore, EPA is expressly required to evaluate exposures from combinations of activities, which it cannot do if it excludes conditions of use at the outset that have been evaluated or regulated by another agency, particularly when that risk management is not an outright ban.

Second, Congress expressly exempted certain regulated chemicals or uses of chemicals from EPA's authority when it defined "chemical substance" in TSCA § 3(2). 15 U.S.C. § 2602(2)(B). For example, "chemical substance" does not include certain materials as defined in the Atomic Energy Act of 1954. *See id.* § 2602(2)(B)(ii), (iv). Thus, when Congress intended for EPA not to regulate certain conditions of use because they were regulated under other specific federal statutes, Congress expressly excluded those conditions of use. That Congress chose a limited, specific set of exclusions indicates that Congress did not intend for EPA generally to ignore other conditions of use even where they fall under other federal regulatory schemes.

D. The scopes contain incoherent and arbitrary and capricious reasoning because of EPA's approach to conditions of use.

EPA's illegal approach to "conditions of use" leads it to put "blinders" on regarding certain uses, exposures, and risks. The result is "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to have considered "factors which Congress has not intended it to consider [and] entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. It also violates several provisions of TSCA § 26 because by ignoring uses, exposures, and related information, EPA will not be acting "consistent with the best available science," EPA will not base decisions on "on the weight of the scientific evidence," and EPA will not "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h), (*i*), (k). In addition, because EPA's distinction is a false one untethered to the information, EPA seems to treat certain conditions of use inconsistently throughout the documents.

For example, in the 1,4-dioxane scope, EPA states that it will not consider risks arising from 1,4-dioxane when it is present as a by-product or residual contaminant from the manufacture of other chemicals. *See* 1,4-Dioxane, Scope at p.21, Docket ID: EPA-HQ-OPPT-2016-0723. But EPA identifies numerous products that "potentially contain[] 1,4-dioxane as a residual contaminant, including paints, coatings, lacquers, ethylene glycol-based antifreeze coolants, spray polyurethane foam, household detergents, cosmetics/toiletries, textile dyes, pharmaceuticals, foods, agricultural and veterinary products," as well as "magnetic tape and adhesives." *Id.* These are known and reasonably foreseen conditions of use

leading to exposures to 1,4-dioxane, and EPA's decision to ignore them when analyzing whether this chemical presents an unreasonable risk is arbitrary and capricious. EPA's theory is that it cannot regulate these impurities until it analyzes ethoxylated chemicals (*id.* at 8), but EPA provides no reasoned legal theory for why it could not act to regulate these exposures after this risk evaluation. *Id.* Even more problematically, EPA staked out the position that "EPA may choose not to include a particular impurity within the scope of any risk evaluation." 82 Fed. Reg. at 33,730. So these exposures may never be analyzed.

In addition, EPA acknowledges that 1,4-dioxane is often used as an intermediate or a reactant and that "the 1,4-dioxane would react either fully *or to a lesser extent*. Following completion of the reaction, the produced substance *may or may not be purified further*, thus removing unreacted 1,4-dioxane (if any exists). Reacted 1,4-dioxane is *assumed* to be destroyed and is thus not expected to be released or cause potential worker exposures." *See* 1,4-Dioxane, Scope at p.56, Docket ID: EPA-HQ-OPPT-2016-0723 (emphases added). But EPA never acknowledges that the unreacted 1,4-dioxane could lead to exposure. And that document provides no explanation, documentation, or quantification supporting the underlying assumption that 1,4-dioxane is destroyed or reacted. Indeed, from the description, it seems clear that it often will not be destroyed. The assumption in the last quoted sentence is contrary to the statements made in the proceeding sentences.

EPA's scopes should indicate that it will assess the reasonably available information on hazards and exposures for the substances (see Section II below), and that information should inform EPA's evaluation of the risks associated with "the conditions of use." If there is a real-world exposure, then EPA should not ignore it.

II. EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA §§ 4 and 8 to obtain additional information.

TSCA orders EPA to consider "available" and "reasonably available" information in crafting a risk evaluation, 15 U.S.C. §§ 2605(b)(4)(F)(i), 2625(k), and under the new risk evaluation rule, EPA defined "[r]easonably available information" to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 C.F.R. § 702.33, promulgated at 82 Fed. Reg. 33,748 (July 20, 2017). Thus, under its own rule, EPA has to consider information that it "can reasonably generate, obtain, and synthesize."

Yet, the scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is *reasonably* available information.

A. Any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities.

EPA must promulgate reasonable regulations under § 8(d) and 8(a) to obtain information about hazards, exposures, and conditions of use for these ten chemicals; EPA should also exercise its authority under § 8(c) to obtain additional information. Consistent with TSCA § 8(a)(5), EPA can take steps to reduce unnecessary and duplicative reporting. Because TSCA requires EPA to produce robust risk evaluations that reflect "reasonably available" information, and information available under these authorities is "reasonably available" on its face, EPA must use these authorities to fulfill its duty. Moreover, these first ten risk evaluations are crucial to establishing the credibility of the TSCA program under the Lautenberg Act, and EPA can only establish that credibility by using its full authority to obtain "reasonably available information" on chemicals, as required by the law. Collecting this information is also necessary to fulfill EPA's duty to use the best available science under TSCA § 26.

TSCA § 8(d) allows EPA to "require any person who manufactures, processes, or distributes in commerce *** any chemical substance or mixture *** to submit to the Administrator—lists of health and safety studies: (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person; or (C) reasonably ascertainable by such person." 15 U.S.C. § 2607(d). EPA should issue § 8(d) rules for these ten chemicals. To obtain a complete picture, EPA should expressly require both manufacturers and processors to report on these chemicals under the § 8(d) rules. *See* 40 C.F.R. § 716.5(c).

EPA has previously issued such rules for some of these chemicals, but two decades have passed since the last of those rules sunsetted, so new, additional health and safety studies are almost certainly available. For example, the methylene chloride and asbestos reporting periods sunsetted in 1992, the HBCD reporting period sunsetted in 1995, and the perchloroethylene reporting period sunsetted in 1997. *See* 40 C.F.R. § 716.120. Given scientific advancement over the last two decades, issuing new rules calling in health and safety studies would likely provide EPA with additional valuable information to assess the hazards, exposures, and risks posed by these chemicals. It appears that EPA has never issued such rules for Carbon Tetrachloride, Trichloroethylene, Pigment Violet 29, 1-Bromopane, 1-4 Dioxane, and N-Methylpyrrolidone. *See* 40 C.F.R. § 716.120. Thus, issuing § 8(d) rules for those chemicals is even more important.

Notably, EPA's regulations correctly interpret "health and safety study" broadly to incorporate "[a]ny data that bear on the effects of a chemical substance on health or the environment." 40 C.F.R. § 716.3. These include numerous tests for health and environmental effects. *See id.* They also include monitoring data and other assessments of human and environmental exposures. *See id.* EPA should also review these studies upon receipt and request underlying data under 40 C.F.R. §§ 716.10(a)(4), 716.40(a). EPA should also separately request reporting on these chemicals when they are manufactured, processed, or distributed as an impurity, 40 C.F.R. § 716.20(a)(9), because impurities may be an important source of exposure and thus risk, as explained above.

Under TSCA § 8(a), EPA may require manufacturers and processors to provide extensive information. *See* 15 U.S.C. § 2607(a)(2). EPA "shall, to the extent feasible" "not require reporting which is unnecessary or duplicative" and also "apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title." *Id.* § 2607(a)(5). To avoid duplication, EPA need not request reporting on information EPA has already obtained through other recent submissions such as through the Chemical Data Reporting (CDR) process. *See* 40 C.F.R. Part 711. But the CDR process does not require manufacturers and processors to provide all information that EPA can reasonably obtain under TSCA § 8(a) which is relevant to the risk evaluations. For example, EPA should require reporting of: "[a]ll existing information concerning the environmental and health effects of" each chemical; "the byproducts resulting from the manufacture, processing, use, or disposal of each" chemical; more detailed information about exposures to these chemicals, including the duration, frequency, and timing of exposures; and additional information about disposal. *See* 15 U.S.C. § 2607(a)(2). In particular, EPA can require submission of any data available on releases or exposures in the workplace and environment, and those data would be crucially important to an accurate risk evaluation. To decrease the burden on industry, EPA should pursue both rulemakings simultaneously, and EPA can provide that when information is submitted under one rule, the same information need not be submitted under the other. But EPA should use both authorities to ensure that it does not miss any information that may fall within one authority but not the other.

In addition, EPA should rely on its request authority under TSCA § 8(c). Under TSCA § 8(c), "[a]ny person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture." 15 U.S.C. § 2607(c). EPA promulgated rules governing this recordkeeping requirement at 40 C.F.R. Part 717. The rules apply to most manufacturers and many processors. 40 C.F.R. § 717.5. Manufacturers and processors must maintain records of many types of allegations, as detailed in 40 C.F.R. §§ 717.5 and 717.10. The regulation defines "significant adverse reactions" to include, but not be limited to, many specific types of harm that are highly relevant to the ultimate question presented in a risk evaluation: "whether a chemical substance presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(b)(4)(A). Firms must maintain these records for 30 or 5 years, depending on the circumstances. 40 C.F.R. § 717.15(d).

EPA should use its authority to request these records on alleged significant adverse reactions caused by the ten chemicals analyzed in the scope documents and add them to the administrative record for the relevant chemical. EPA can request records from manufacturers and processors that reported the chemicals in response to any § 8(a) and 8(d) rules or in response to CDR reporting. *Id.* § 717.17. EPA can request those records by letter. *Id.* § 717.17(b). Finally, EPA can also notify all people holding such records to provide them by a notice in the Federal Register. *Id.* These records may provide valuable information on hazards, exposures, and conditions of use, since the records may reveal not only significant adverse reactions but also information about the specific exposure and use that may have caused the reaction.

B. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps.

EPA should make robust use of its § 4 authority to fill any gaps in information. EDF recognizes that time constraints apply to these first ten chemicals and thus some types of testing may not be possible, but going forward, EPA needs to use its authority fully and do so in a timeframe that ensures it will have all of the information it needs to conduct risk evaluations.

As EPA moves forward on the first 10 risk evaluations, it should first clearly identify *all* significant information gaps on hazards or exposures. Based on its own regulation, EPA must then use its authority under TSCA § 4(a)(2) to require the development of new information to fill those gaps wherever possible. Information that EPA can generate under TSCA § 4(a)(2) is reasonably available under EPA's own regulation as "information that EPA *** can reasonably generate [and] obtain *** for use in risk evaluations." 40 C.F.R. § 702.33. Thus, EPA should identify such information gaps and then promptly require the conduct of all testing that can be done and still meet the statutory deadlines for the risk evaluations.

TSCA § 4(a)(2) provides that EPA "may, by rule, order, or consent agreement require the development of new information relating to a chemical substance *** if the Administrator determines that the information is necessary *** to perform a risk evaluation under section 6(b)." 15 U.S.C. § 2603(a)(2)(A)(i). Congress provided this additional testing authority allowing EPA to require testing or other data development efforts solely upon a determination "that the information is necessary *** to perform a risk evaluation under section 6(b)." *Id.* In light of deadlines, EPA can and should use its order authority and does not need to make the additional findings required for a rule under TSCA § 4(a)(1).

In places in these scopes, EPA seems to be going out of its way to avoid using its information authorities. For example, in numerous places in these scopes, with respect to exposure, EPA indicates that "[f]or conditions of use where data are limited or not available, [it will] review existing exposure models that may be applicable in estimating exposure levels" (p.43). This language suggests that EPA will simply default to models rather than use its authority to get needed information. In EDF's view, EPA should first use its authorities under TSCA §§ 8 and 4 to fill those information gaps, rather than rely on models to compensate for lack of information. This is not to say that exposure models do not have a role, but they are not a basis for avoiding the obligation to collect information.

Our review of the scopes indicates that there are significant gaps in the information. Where possible EPA needs to fill those gaps. When it is not possible, consistent with TSCA § 26, EPA needs to identify those gaps and characterize the uncertainty in the draft risk evaluations. To cite just one example, in the scope for Methylene Chloride EPA completely fails to mention an information gap earlier identified in the Work Plan. Specifically, the 2014 Work Plan Assessment for Methylene Chloride identified both developmental neurotoxicity and immunotoxicity from chronic exposure as important data gaps, impacting the selection of the point of departure:

> There is uncertainty about chronic exposure impacts on the nervous system function. The nervous system has been well studied and identified as very sensitive for acute effects. However, there is a paucity of data on chronic neurological impacts, especially developmental neurotoxicity. Likewise, there is limited information about immunotoxicity following chronic exposure to DCM. Existing hazard studies are not sufficient for dose response analysis to provide a lower point of departure than existing adverse findings in the liver from chronic exposures."

See Methylene Chloride: Paint Stripping Use, TSCA Work Plan Chemical Risk Assessment at p.115, https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf

C. If EPA already has relevant information, it is reasonably available and EPA should consider it.

The strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." *See, e.g.*, Asbestos literature at p.13. But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation *** is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available, EPA must review it.

In addition, much of this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. First, historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act. Second, the Lautenberg Act greatly increased the requirements companies must meet to assert CBI claims. For example, information only qualifies for protection if the submitter asserts *and* substantiates that it has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c). Thus, even if the information once merited protection, it may no longer be confidential under the standards of TSCA § 14. Third, as a general rule, TSCA § 14(b)(2) provides that health and safety studies and information from health and safety studies are not entitled to confidential treatment, so much of this information may not be confidential under that provision.

To fulfill its duties under TSCA, EPA must review this reasonably available information and identify that which is potentially relevant to the risk evaluations. Where information is relevant, EPA should also consider whether the information meets the strict requirements for nondisclosure under TSCA § 14. If not, EPA should add it to the administrative record for review by the public. Whether or not it meets those requirements, EPA should then determine whether and how to consider the information in evaluating these chemicals. Notably, TSCA § 26(j) requires that, "subject to section 14," EPA "shall make

available to the public *** a list of the studies considered by [EPA] in carrying out each such risk evaluation, along with the results of those studies." 15 U.S.C. § 2625(j).

D. When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information.

In the literature searches, EPA sometimes states that it relied on recent assessments, and then only performed research for dates beyond those assessments. *See, e.g.*, 1,4-Dioxane, Strategy for Conducting Literature Searches for 1,4-Dioxane: Supp. File for the TSCA Scope at p.7, 9-10, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0047. EPA needs to provide a short analysis presenting its review of the prior analysis to ensure it adequately captured and addressed all reasonably available information as of the date of its publication, particularly given the expanded obligations under the Lautenberg Act. If EPA finds it was not adequate, then EPA should broaden its literature search.

III. EPA needs to take additional steps to ensure both the completeness and accuracy of the information it relies upon.

As explained above, EPA should rely on its authorities under TSCA §§ 8 and 4 to obtain all reasonably available information. Those authorities include a number of measures to ensure the accuracy and completeness of the data relied upon. To the extent EPA relies on voluntarily submitted information, EPA needs to take additional steps to ensure the accuracy and completeness of the information. Otherwise, EPA will violate TSCA § 26 by failing to make decisions "in a manner consistent with the best available science." 15 U.S.C. § 2625(h)

A. EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals.

EPA has requested in each of the scopes that industry and other stakeholders provide information. While this voluntary request was a reasonable first step towards obtaining the necessary information, EPA has failed to provide any account for how this voluntary approach to collecting information will result in EPA obtaining all "reasonably available" information as EPA has defined that term. There are several obvious problems and limitations with this voluntary approach which EPA has not even acknowledged, much less addressed.

First, a voluntary call is much less likely to produce all of the necessary information than rules mandating that affected parties provide the requested information. If manufacturers and processors are legally required to provide the information, that legal obligation provides a strong incentive for them to collect and submit all relevant information. Absent that incentive, some companies may choose to focus time and attention on other matters. Indeed, the burdens (whether one considers them heavy or light) of collecting and submitting information counsel in favor of issuing mandatory rules. *If* the process of

collecting and submitting the information is not onerous or difficult, then using rules to require the submission of the information will do little if any harm to the regulated industry, and use of rules will ensure EPA has a complete picture and increase credibility. Alternatively, to the extent that the process is onerous or difficult, it is even more important that EPA *require* the submission of the information, because otherwise those burdens will likely discourage stakeholders with relevant information from collecting and submitting the information.

Second, EPA has provided no empirical evidence establishing that this voluntary approach will result in EPA obtaining all "reasonably available" information. Unless EPA has some empirical basis for stating that the voluntary approach will allow EPA to obtain all reasonably available information that it can obtain under its legal authorities, EPA must rely on its existing authorities to obtain a complete set of information.

Indeed, EPA's prior experience with voluntary reporting provides strong evidence that a voluntary approach is unlikely to provide complete and accurate data. For example, an EPA advisory committee called for the development of nanomaterial reporting rules in 2005, but EPA instead spent several years developing and carrying out a voluntary reporting program, the Nanoscale Materials Stewardship Program (NMSP). This voluntary reporting program produced minimal information as revealed by EPA's 2009 interim report on the NMSP. Nanoscale Materials Stewardship Program, Interim Report, OPPT (Jan. 2009), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0003. "[I]n the report EPA estimated that companies provided information on only about 10 percent of the chemical substances manufactured at the nanoscale that may be commercially available in 2009." 80 Fed. Reg. 18,330, 18,334 (April 6, 2015). In 2017, over a decade after the data need was identified, EPA finally finalized a § 8(a) reporting rule to acquire the data. 82 Fed. Reg. 3641 (Jan. 12, 2017). Given the past failures of voluntary approaches, EPA should not rely on them here.

Third, manufacturers and processors of these chemicals have a vested interest in EPA finding that the chemicals do not present an unreasonable risk. A no-unreasonable-risk finding reduces the likelihood of government regulation, including potential restrictions on risky chemicals, and it may reduce any stigma they may otherwise face in the marketplace. The financial costs of regulation may ultimately be very high for some specific firms and individuals, and even if not, many firms and individuals may *believe* that the costs of regulation will be high. These companies have a "financial interest" in the outcome of these proceedings, and they are not impartial. *See, e.g.*, 28 U.S.C. § 455(b)(4) (requiring Judges to disqualify themselves in proceedings where they have a financial interest). Because of this reality and appearance of partiality, relying solely on voluntary measures decreases the credibility of these risk evaluations.

Relying solely on voluntary presentation of information raises the concern that the companies or trade associations may present an incomplete or skewed picture. Companies and trade associations may choose to "cherry pick" information and provide only the information that paints their chemicals in favorable light. They may provide only summaries of information that reflect conscious and subconscious judgment calls that result in unduly favorable conclusions; and without access to the full information neither EPA nor the public can independently assess such conclusions. They may choose

not to review records robustly when the review may disclose unfavorable information. They may seek to put their best foot forward and describe the ideal scenario of use and safety measures. Or, if they have unfavorable information, they may choose not to provide any information at all and simply not participate in these proceedings.

To be sure, members of the regulated community are crucial sources of information about their chemicals' uses, hazards, and exposures, but EPA cannot simply assume that they will voluntarily disclose unfavorable or complete information about their practices and products. *See* THE FEDERALIST NO. 51 (James Madison) ("If men were angels, no government would be necessary. *** [E]xperience has taught mankind the necessity of auxiliary precautions."); *Williams v. Pennsylvania*, 136 S. Ct. 1899, 1905-06 (2016) ("Bias is easy to attribute to others and difficult to discern in oneself. *** This objective risk of bias is reflected in the due process maxim that 'no man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome.'"). Here, manufacturers and processors obviously have an interest in the outcome, and EPA must craft its procedures and approaches with that reality in mind. Requiring the submission of information is the safest approach to ensuring that these parties provide all relevant information, and that is in turn crucial to establishing and demonstrating the credibility of this process.

If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information. First, EPA can require that certain information and underlying information be provided in full, which ensures completeness. In addition, a § 8(d) rule requires that people engage in an adequate search of records. 40 C.F.R. § 716.25. Second, submitters must file certification statements by authorized officials that certify that the submitted information has been submitted in compliance with the requirements of this process. *See, e.g.*, 40 C.F.R. § 711.15(b)(1). Third, submitters often must retain records of required submissions for a period of five years, and the retention of records can help encourage accurate reporting since those records would be available should a submission latter be investigated. *See, e.g.*, 40 C.F.R. § 711.25. None of these features apply to the voluntary requests for information EPA has indicated it is relying on.

In addition, as EDF has explained in prior comments, there are numerous reasons that it is important that the public have access to full studies and the underlying information, not simply robust or other study summaries. *See, e.g.*, EDF Comments on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act, Comment at p.37, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074. Without access to full studies, the public will be challenged or unable to assess and comment on the quality of the studies used by the agency. *Id.* EDF reincorporates and reiterates the numerous points made in support of public access to the full studies here. *Id.* These points also support the importance of EPA obtaining the full studies.

B. For voluntary submissions, EPA should take additional steps to ensure completeness and accuracy and to vet information based on underlying data.

To the extent it relies on voluntary submissions, EPA can and should take additional steps to better ensure that the voluntary information it receives is accurate and complete. EPA would need to develop a far more rigorous and structured process than it currently has. For example, EPA's submission process does not appear to require anyone to certify that the information in their comments is accurate or complete to the best of their knowledge. EPA should consider approaches for vetting statements and assertions, particularly when made by entities with a financial interest in the outcome of these risk evaluations.

EPA should also request that submitters always provide full studies, as well as underlying data whenever reasonably available or obtainable. Setting aside concerns about partiality, EPA needs the underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular submission.

In addition, EPA should seek input directly from workers for manufacturers and processors, providing them an easy method to submit information on workplace practices and conditions independently from management. EPA needs to take steps to allow workers to provide input in a manner that reduces the risks of any potential retaliation from management.

To give a few specific examples from the scopes:

In the Perchloroethylene scope (also known as tetrachloroethylene or PCE), EPA cites the Vinyl Institute's comments for the fact it can be a residual or byproduct in the manufacture of other chemicals. *See* Perchloroethylene, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0732 (citing comment at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0013). That comment, in turn, contains a table claiming to summarize the approximate concentrations of Perchloroethylene in light and heavy end liquid intermediate streams yielded in the EDC/VCM process for manufacturing each of four chlorinated organic substances. The comment states that there is no residual Perchloroethylene in light liquid ends and 1.1% by typical weight in heavy liquid ends. But the comment does not provide or cite any underlying data supporting these findings. When commenters provide summary statements along these lines, EPA should give them little weight unless it also receives the underlying data to ensure that the reported results or conclusions drawn accurately reflect real-world conditions and to assess the level of certainty and scope of applicability that EPA can attribute to the results or conclusions. This point holds for all of the percentages set forth in that table, including those for the other three products.

Similar concerns arise for many of the other scopes. For example, in the Carbon Tetrachloride scope, EPA states that: "there are public comments, EPA-HQ-OPPT-2016-0733-0005 [3M] and EPA-HQ-OPPT-2016-0733-0017 [ACC], stating that carbon tetrachloride may be present in a limited number of industrial products with chlorinated ingredients at a concentration of less than 0.003% by weight." Carbon Tetrachloride, Scope at p.20, Docket ID: EPA-HQ-OPPT-2016-0733. But upon examining those

comments, they do not provide any of the underlying data or enough information to assess accuracy of the statement or the level of uncertainty that should apply to the results. The ACC comment is particularly difficult to assess. It involves multiple levels of hearsay, with ACC reporting statements that companies reported to it. Some of those companies acknowledge they are also relying on hearsay from suppliers and have not taken steps to confirm these concentrations. Those suppliers might also be relying on hearsay; it is simply not clear what the bases are for some of these values. Hearsay is, of course, particularly problematic when the statement serves the interest of the person submitting the evidence. *See, e.g.*, FED. R. EVID. P. 804(b)(5) (exception for statements against interest). As such, these concentrations arguably provide at best a "lower bound" estimate; they are not sufficient in terms of establishing that the actual concentrations are not higher. While no formal hearsay rule applies to these administrative proceedings and the hearsay evidentiary rule generally has limited applicability to technical studies and business records, it is relevant to the weight EPA should give these reported values given these circumstances. ACC does not disclose the companies providing the information, making it impossible for EPA to independently address these kinds of concerns. In addition, ACC's comment often fails to provide any clarity or detail as to how the concentrations were measured or assessed, much less provide the data underlying these claimed concentrations. The ACC comment asserts concentrations for 1,4-Dioxane, Pigment Violet 29, N-Methylpyrrolidone (NMP), Methylene Chloride (DCM), Carbon Tetrachloride, and HBCD, but for most of these concentrations, it is impossible for EPA or the public to assess whether they are accurate. For some of these concentrations, the comment states that Safety Data Sheets and Technical Data Sheets are provided with the comments, but EDF did not find any attachments with the comment containing those materials. In sum, EPA needs to scrutinize these voluntary submissions carefully and ensure access to the underlying information, which is necessary to assess the accuracy of the statements therein.

In the asbestos scoping document, EPA acknowledged that the analysis of the Chlor-Alkali industry was "primarily based on information provided by either the chlor-alkali industry or [the American Chemistry Council] and is meant to represent typical practices." *See* Asbestos, Scope at p.54, Docket ID: EPA-HQ-OPPT-2016-0736. EPA correctly recognized that EPA should "further evaluate how representative the processes witnessed at these two facilities are of processes at other plants." *Id.* at 23. EPA should take measures to ensure that its process will in fact accurately assess the full range of existing practices, relying on independent data where possible. Where independent data are unavailable, EPA should reach out to workers directly to better determine actual practices. Even when companies have good practices on paper, those practices may not be the reality on the ground.

EPA also needs to carefully scrutinize statements to ensure it correctly interprets them.

IV. These scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations.

Broadly viewed, the scopes do not meet several of the statutory requirements of TSCA. TSCA § 6(b)(4)(D) requires that EPA "shall, not later than 6 months after the initiation of a risk evaluation,

publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D). These scopes do not fully satisfy these requirements. Some aspects are plainly illegal under *any* interpretation of the statute, for the reasons given above, such as the statement that "EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11).[1] But many other aspects, while problematic, can be resolved by EPA in the next step: its development of problem formulations.

It is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. EDF believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified. With respect to susceptible populations, EPA should consider workers and, in most cases, pregnant women and children, to be potentially exposed or susceptible subpopulations. We identify below a number of specific examples where EPA's scopes are unclear and merit further study.

A. 1,4-Dioxane

EPA states: "EPA evaluated the weight of the evidence for cancer in humans and animals and concluded that 1,4-dioxane is 'likely to be carcinogenic to humans' based on evidence of carcinogenicity in several 2-year bioassays." 1,4-Dioxane, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0723. However, certain language in this section suggests that EPA may not include cancer as a hazard endpoint in the risk evaluation.

Indeed, EPA almost seems to suggest that inconclusive evidence regarding the "mode of action by which 1,4-dioxane produces liver, nasal, peritoneal (mesotheliomas) and mammary gland tumors" might form a basis for disregarding the evidence of such hazards. *Id.* at 35. As a general matter, EPA should not exclude observed hazards simply because the underlying MOA is not fully delineated or understood, doing so would significantly and inappropriately jeopardize the robustness and health-protections of the risk evaluation. If there is evidence of hazard, EPA should include it in the risk evaluation, even if the precise mode of action is not yet understood.

[1] As explained above, EPA puts too much weight on a floor statement from a single Senator, David Vitter. But even Senator Vitter stated that EPA must consider all conditions of use identified in the scope. *See* 114 Cong. Rec. S3520 (daily ed. June 7, 2016) (statement of Sen. Vitter). Despite that statement, the scoping documents all state that "during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11). Thus, EPA is inconsistent in how much weight it gives to Senator Vitter's statements, and EPA's current interpretation appears to contradict the views expressed throughout the legislative history by every single legislator. If EPA excluded uses identified in the scope, such as uses in the chlor-alkali industry (e.g., pp.20, 23-24), then EPA will be acting contrary to Senator Vitter's statement.

B. Perchloroethylene

The scope for Perchloroethylene states that "EPA expects to consider hazards identified in the recent assessment by the EPA Integrated Risk Information System (IRIS) Program: neurotoxicity, kidney toxicity, liver toxicity, developmental and reproductive toxicity and cancer. Support for an association with immune and blood effects was less well characterized." Perchloroethylene, Scope at p.11, Docket ID: EPA-HQ-OPPT-2016-0732. It is unclear from the scope whether EPA intends to include immune and blood effects in particular.

C. Trichloroethylene (TCE)

In the scope for TCE, EPA suggests that TCE's use as a spot remover will not be analyzed because it was previously analyzed in a risk evaluation. TCE, Scope at p.25, Docket ID: EPA-HQ-OPPT-2016-0737. That approach may be reasonable if EPA finalizes its proposed ban on this use of TCE to address those risks, as discussed more below. But that approach only applies to those spot remover uses that have previously been analyzed, specifically commercial dry cleaning facilities. This risk evaluation needs to consider TCE's use as a consumer spot remover. Those uses have not been analyzed in-depth, and the 2014 work plan assessment recognized that some such products may contain TCE as a main ingredient. *See* Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses, TSCA Work Plan Chemical Risk Assessment at p.52, https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

D. N-Methylpyrrolidone (NMP)

The NMP scope has numerous inconsistencies with respect to its identification of the endpoints to be assessed. EPA begins by acknowledging that a "number of human health hazards have been identified for NMP including adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems." N-Methylpyrrolidone, Scope at p.36, Docket ID: EPA-HQ-OPPT-2016-0743. EPA also states that: "EPA expects to consider all potential hazards associated with NMP." *Id.* EDF completely agrees with that approach. However, the description under section 2.42 Human Health Hazards indicates that EPA intends to focus on a narrower set of hazards (acute toxicity and reproductive/developmental toxicity), and provides no justification or even explanation for excluding some of the hazards that it previously identified.

E. Potentially exposed or susceptible subpopulations

EPA also does not identify pregnant women, women of childbearing age, or the developing fetus as potential exposed or susceptible subpopulations for either N-Methylpyrrolidone (NMP) [NMP, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0743] or TCE [TCE, Scope at pp.37-38, Docket ID: EPA-HQ-OPPT-2016-0737], despite the fact that EPA's previous risk assessments on these two chemicals identify women of childbearing age and the developing fetus as a primary susceptible population (in addition to workers). EPA's failure to identify these populations in the scopes is both contrary to law and an abuse of discretion. TSCA § 3(12) defines "potentially exposed or susceptible subpopulation" to include "a

group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance *** , such as infants, children [or] pregnant women." 15 US.C. § 2602(12). Here, EPA has previously found that "women of childbearing age" are at greater risk of adverse health effects from these chemicals. 82 Fed. Reg. 7432, 7434 (Jan. 19, 2017); 82 Fed. Reg. 7464, 7467 (Jan. 19, 2017).

Furthermore, TSCA requires that EPA identify "the potentially exposed or susceptible subpopulations the Administrator expects to consider" in the scopes. 15 US.C. § 2605(b)(4)(D). While EPA has considered those at greater risk due to *increased exposure* in the scopes to some extent, the agency appears to defer the process of identifying populations with *greater susceptibility* to the problem formulation or risk evaluation stage: "In developing the hazard assessment, EPA will also evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s)." *See, e.g.*, NMP, Scope at pp.36-37, Docket ID: EPA-HQ-OPPT-2016-0743; 1,4-Dioxane, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0723.

V. EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures.

The scoping documents generally acknowledge the need to analyze activities related to a chemical's distribution, but EPA will need to analyze these exposures more robustly than the scopes currently reflect. *See, e.g.*, 1,4-Dioxane, Scope at p.22, Docket ID: Docket ID: EPA-HQ-OPPT-2016-0723.

The scoping documents give little, if any, attention to potential releases and exposures resulting from accidental releases. EDF does not suggest that EPA needs to consider every possible scenario, but the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks. For example, as and after Hurricane Harvey passed through Houston, over 40 sites released toxic chemicals into the environment. *See, e.g.*, More Than 40 Sites Released Hazardous Pollutants Because of Hurricane Harvey, https://www.nytimes.com/interactive/2017/09/08/us/houston-hurricane-harvey-harzardous-chemicals.html?_r=0. Given the *known* accidental releases, the huge number of petrochemical plants and refineries in the Houston area, and the likelihood that flooding there may become more common in light of climate change, such events are clearly reasonably foreseen and hence EPA needs to give more consideration to the potential for accidental releases.

VI. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures.

Language used in the scopes suggests that EPA may inaccurately assume that people comply with all warning labels and always use personal protective equipment (PPE). EDF strongly urges EPA to consider real-world exposures reflecting the reality of the sometimes low-compliance with or non-existence of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by

either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). And absent empirical evidence establishing the extent to which people are using these measures, EPA should assume that they may not be. Indeed, EPA's need for accurate information about actual compliance is another reason to rely on its authorities under TSCA § 8 to mandate that manufacturers and processors provide that information. In addition, it bears noting that reliance on PPE as a primary measure to protect workers is counter to OSHA's Industrial Hygiene Hierarchy of Controls (HOC), a long-standing principle that prioritizes measures to eliminate or reduce the presence of a hazard in occupational settings (e.g., substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves, such as through reliance on PPE and warning labels. The HOC exemplifies the best available science for creating safe, healthful workplace environments.

As an example of a problematic reference to PPE in the scopes, in the asbestos scope, EPA stated that "[d]ermal exposure is unlikely due to glove use in the workplace." Asbestos, Scope at p.37, Docket ID: EPA-HQ-OPPT-2016-0736. But EPA cites no evidence supporting this assumption. While gloves may be used in many workplaces, EPA needs to provide evidence of the extent of such use. Among other things, EPA correctly noted earlier that "certain conditions of use, such as a mechanic changing asbestos-containing brakes, may also result in dermal exposure." *Id.* at 35. Is there any evidence that all or even most mechanics wear gloves when changing brakes? Indeed, EPA should identify mechanics as a relevant potentially exposed or susceptible subpopulation based on their exposure to brakes.

In comments EDF has submitted in these dockets, EDF previously commented on the serious limitations of labeling and PPE, as well as the importance of adherence to the hierarchy of controls to limit workplace exposures. *See, e.g.*, EDF comments at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0046, March 15, 2017; and at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052, November 21, 2016. EDF reincorporates and reiterates the points made in those comments here.

VII. EPA's decision not to examine uses addressed by its planned § 6(a) rules governing certain uses of TCE, DCM, and NMP is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses.

For Trichloroethylene (TCE), Methylene Chloride (DCM), and N-Methylpyrrolidone (NMP), EPA states that conditions of use previously examined will not be re-evaluated. TCE, Scope at p.9, Docket ID: EPA-HQ-OPPT-2016-0737; DCM, Scope at p.29, Docket ID: EPA-HQ-OPPT-2016-0742 ("This includes uses assessed in the U.S. EPA (2014a) risk assessment and therefore those uses are out of scope for the risk evaluation."); NMP, Scope at pp.20, 28, Docket ID: EPA-HQ-OPPT-2016-0743 ("This includes uses assessed in the previous EPA risk assessment (U.S. EPA, 2015) and therefore those uses are out of scope for the risk evaluation."). EPA has previously found these uses even by themselves present unreasonable risks to human health. In addition, these uses have the potential to increase the total

exposure of people to these chemicals. As a result, EPA can only reasonably exclude these uses if it finalizes the proposed rules to ban these uses. EDF strongly supports those bans for the reasons it articulated in its prior comments.

If EPA does not finalize these bans, then excluding these uses is both contrary to law and arbitrary and capricious. By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses *unless* EPA has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals.

* * * * *

EDF appreciates the opportunity to provide comments and EPA's consideration of them.

Environmental Defense Fund Comments on

Ten Scopes under the Toxic Substances Control Act

Docket IDs: EPA-HQ-OPPT-2016-0725 (Pigment Violet 29), EPA-HQ-OPPT-2016-0723 (1-4, Dioxane), EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene), EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride), EPA-HQ-OPPT-2016-0735 (HBCD), EPA-HQ-OPPT-2016-0736 (Asbestos), EPA-HQ-OPPT-2016-0737 (Trichloroethylene), EPA-HQ-OPPT-2016-0741 (1-Bromopropane), EPA-HQ-OPPT-2016-0742 (Methylene Chloride), and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone)

Submitted Tuesday September 19, 2017

The Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the scopes for the risk evaluations for the first ten chemicals being evaluated under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

In addition to specific comments on each chemical, EDF is providing broad comments addressing the scopes of risk evaluations for the first 10 chemicals as well as others in the future. While our comments are broadly applicable to all of the scope documents, we include examples from specific scopes to illustrate flaws and limitations.

As explained below, these scopes deviate from certain requirements of the law and in places are too unclear and vague or ambiguous to allow us to provide definitive comments. EDF recognizes that EPA was working under tight deadlines in producing these scopes – a problem it further exacerbated by EPA's decision to make major, late changes to the risk evaluation rule. EPA should take advantage of the upcoming problem formulation stage to address the many problems we identify below, and to more clearly and transparently explain its plans for these risk evaluations.

Before discussing the merits of the scoping documents, EDF provides the following clarification about its citation approach. Each scoping document contains largely identical, boilerplate language providing the agency's overall legal approach to "conditions of use" as well as its approaches on some other issues. Indeed, each document includes the same typos or misquotes of the underlying law. For ease of reference and to reduce excessive citations, EDF quotes from the asbestos scoping document and provides simply the page number when addressing these broader legal problems that are present in each scoping document. These comments equally apply to all scoping documents since they all contain

this same language; the only difference is page number. When EDF is specifically quoting another scoping document, we provide a citation clarifying that point.

Contents:

I. TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use.

EPA's scoping documents (pp.11-13) state that EPA has determined that "certain activities may not generally be considered to be conditions of use" (p.11) and also that EPA may "exclude certain activities that EPA has determined to be conditions of use" (p.12). EPA's approach asserts that EPA is allowed to ignore numerous circumstances falling within the statutory definition of "conditions of use" and is contrary to law. For the current set of chemicals under review, EPA may well be ignoring circumstances leading to ongoing exposures, and as a result, will fail to evaluate the risks the chemicals actually pose to human health and the environment.

TSCA's language and structure unambiguously foreclose EPA's interpretation. EPA's decision to disregard certain uses and exposures is also "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to consider "factors which Congress has not intended it to consider [and] entirely fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, as the scoping documents themselves reveal, this approach leads to irrational and arbitrary applications. Instead, EPA should be guided by the statutory language and consider all of those circumstances falling within the definition of "conditions of use." EPA should evaluate all of the circumstances revealed by the evidence of use and exposure, not ignore evidence because of self-imposed blinders.

A. The plain text, overall structure, purpose, and legislative history of TSCA indicate that EPA has to determine whether a chemical substance presents an unreasonable risk comprehensively, under all of its conditions of use.

i) *The plain text requires EPA to consider all conditions of use.*

Statutory interpretation should begin, as always, with the language of the statute. The plain language of both the risk evaluation provision and the definition of conditions of use support the interpretation that EPA must consider all circumstances falling within the statutory definition of "conditions of use." The main risk evaluation provision, TSCA § 6(b)(4)(A), directs that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). Inserting the statutory definition of conditions of use, this provision provides that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* §§ 2605(b)(4)(A), 2602(4). Thus, EPA has to analyze the risks of a substance under the circumstances described in the definition of "conditions of use," and no qualifying language allows EPA to exclude circumstances within that definition. The clause "as determined by the Administrator" calls for a factual finding or determination to be made by EPA. The relevant dictionary definition of "determine" is to "ascertain or establish exactly, typically as a result of research or calculation." OXFORD

AMERICAN DICTIONARY 474 (3d ed. 2010). While EPA may exercise reasonable judgment when interpreting "reasonably foreseen," nothing in this language grants EPA discretion to *ignore* factual circumstances that fall within the definition of "conditions of use." Indeed, statutes often direct agencies "to determine" things or make "determinations," and it is understood that the agency must make the finding required by the statutory language.

EPA's position that it can ignore known and foreseeable uses violates the text of the law. In the scoping documents, EPA asserts that it may ignore "legacy uses" and "associated disposals," impurities, alleged "de minimis" exposures, intermediates, conditions of use within closed systems, and conditions of use that have been analyzed by another regulatory agency (p.12). But "conditions of use" expressly includes "the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen to be to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). And every one of those circumstances is a "known" or "reasonably foreseen" "manufacture", "process[ing]," "use," or "disposal of" a chemical substance. Congress expressly chose to define "conditions of use" broadly to include not only "intended," but also "known" or "reasonably foreseen" manufacture, processing, distribution, use, and disposal. 15 U.S.C. § 2602(4). Disregarding chemical substances present as impurities or byproducts in the scoping documents, for example, because they are not "intended" essentially reads the other two scenarios out of the statute. Similarly, all the other identified conditions of use are also "intended, known, or reasonably foreseen." For example, EPA's scope suggests that 90% of the domestic production of Pigment Violet 29 "is processed as a site-limited intermediate." Pigment Violet 29, Scope at p.19, Docket ID: EPA-HQ-OPPT-2016-0725. It would absurd to ignore these intermediate uses when analyzing this chemical; doing so will lead to a truncated and incomplete analysis. Similarly the decision to exclude 1,4-dioxane's presence in numerous consumer, commercial, and industrial products as a byproduct of ethoxylation is entirely inappropriate, and will result in deficient and erroneous evaluation and determination of the chemical substance's risks. The same points can be made for many of the other chemicals used as intermediates or present as byproducts of chemical or product manufacture.

In contrast to the correct interpretation, EPA's new interpretation finds no support in the text. In the final risk evaluation rule (82 Fed. Reg. 33,726, 33,729 (July 20, 2017)), the only statutory textual basis for EPA's theory appears to be the "expects to consider" clause in the scope provision, TSCA § 6(b)(4)(D), requiring EPA to "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator *expects to consider*." 15 U.S.C. § 2605(b)(4)(D). But "expects to consider" does not mean "chooses to consider" or "prefers to consider." It is not the language of discretion; it is temporal language of anticipation or prediction. The dictionary definition of "to expect" is to "regard (something) as likely to happen." OXFORD AMERICAN DICTIONARY 609 (3d ed. 2010). This language indicates that, in the scope, EPA should describe what it anticipates studying, but it does not state that EPA has discretion to choose to ignore intended, known, or reasonably foreseen uses, hazards, or exposures. Moreover, the provision dictating what EPA must consider during a risk evaluation does not limit EPA's analysis to conditions of use identified in the scope. 15 U.S.C. § 2605(b)(4)(F). Indeed, EPA must consider all such conditions to fulfill its requirement that EPA account for the "likely duration, intensity, frequency, and

number of exposures under the conditions, where relevant." 15 U.S.C. 2605(b)(4)(F)(iv). Thus, the statutory language does not support EPA's assertion of discretion, including EPA's decision to limit its analyses to those factors identified in each scope. For example, under the rule of the last antecedent, the phrase "the Administrator expects to consider" does not even *modify* "conditions of use" or "hazards" or "exposures." Notably, EPA has so little regard for the statutory language that it repeatedly misquotes this language in significant ways.

Textually, EPA's argument also directly conflicts with TSCA § 26(k). 15 U.S.C. § 2625(k). TSCA § 26(k) requires EPA to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." *Id.* Notably, this requirement does not include *any* conditional phrase that modifies "conditions of use." And Congress included this provision to ensure that EPA could not ignore "reasonably available" "information relating to a chemical substance or mixture"; the purpose of this provision is to compel EPA to consider all reasonably available information. It would undermine this directive if EPA chooses to arbitrarily ignore certain uses and related exposures.

ii) *TSCA's overall structure requires EPA to consider all of the conditions of use.*

TSCA provisions direct EPA to prepare risk evaluations and the related findings for "chemical substances," *as a whole*, not for specific or limited conditions of use of those substances. For example, the risk management provision expressly requires EPA to address risks when the risks arise from combined exposure. TSCA § 6(a) provides that: "If [EPA] determines in accordance with [the risk evaluation provision] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, *or that any combination of such activities*, presents an unreasonable risk of injury to health or the environment," then EPA must issue a risk management rule. 15 U.S.C. § 2605(a); *see also* 15 U.S.C. § 2608(a) (using same language in provision governing requests to other federal agencies to address risks). Thus, if "any combination" of conditions of use presents an unreasonable risk, EPA must issue a risk management rule. But EPA must analyze *all* of these activities to assess whether *any combination* presents a risk.

When describing the end of a risk evaluation, TSCA requires EPA to make a finding about the "chemical substance" with no reference to conditions of use. *See, e.g.*, 15 U.S.C. § 2605(c)(1), (*i*) ("If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A)," then EPA must issue a regulation to address the unreasonable risk.). The absence of any reference to conditions of use makes it clear that EPA must make a finding for a chemical substance as a whole, not one limited to certain conditions of use. Notably, in the final prioritization rule, EPA correctly reasoned that this type of language indicated that EPA had to consider *all* uses in prioritization. *See* 82 Fed. Reg. 33,753, 33,755 (July 20, 2017) ("The statute directs EPA to make prioritization determinations on a 'chemical substance' or 'substance,' not on 'uses,' *see, e.g.*, 15 U.S.C. §§ 2605(b)(1)(A)-(C), and in most cases, without reference to 'the conditions of use.'"). This reasoning equally applies to risk evaluations.

iii) *TSCA's purpose, as well as basic logical reasoning and the best available science, require EPA to consider all conditions of use to assess a chemical substance as a whole.*

The purpose of the risk evaluation is to analyze the risks of a substance based on an assessment of its hazards and exposures. Ignoring potential exposures at the outset undermines that purpose. And science and logic do not support EPA's exceptions. For example, EPA states that it may disregard so-called "de minimis" exposures from conditions of use that occur in a closed system or use as an intermediate (p.12). But intermediates are often not completely consumed in chemical reactions and may remain as a residual in final reaction products. *See, e.g.*, California Department of Toxic Substances Control, Spray Polyurethane Foam Systems Containing Unreacted Methylene Diphenyl Diisocyanates, http://www.dtsc.ca.gov/SCP/Spray_Polyurethane_Foam.cfm (last visited Sept. 18, 2017). So the presumption that intermediates lead to a "de minimis" exposure is often contrary to the scientific evidence. In addition, intermediates must still be manufactured as well as typically being stored, transferred, or distributed, all of which are activities that can lead to exposures – including to workers, whom TSCA expressly identifies as a "potential exposed or susceptible subpopulation." Similarly, unintended impurities or contaminants can nonetheless lead to exposures and hence risks to human health or the environment, the significance of which needs to be determined in conducting a risk evaluation. *See infra* at pp.10-11 (discussing 1,4-dioxane). Ignoring them at the outset is contrary to the purpose of TSCA and risk evaluations, as well as the law's requirement that EPA rely on the best available science.

To be sure, EDF generally agrees with EPA's statement that "all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk." 82 Fed. Reg. at 33,734. Legally, EPA may be able to provide a concise and scientifically valid finding that a particular condition of use—such as the use phase of a chemical used as an intermediate—leads to little or no exposure and risk in a particular case, based on less than an in-depth analysis. And TSCA does not require a quantitative evaluation when a qualitative evaluation is determined and documented to be appropriate. But TSCA does not authorize EPA to simply "exclude" conditions of use at the outset as a matter of legal discretion. Furthermore, EPA must provide a scientific, data-backed rationale for why it decides a less extensive evaluation is sufficient, and cannot merely rely on a lack of data for such a decision.

EPA is imposing blinders on its analysis by asserting its authority to refuse to look at certain conditions of use, including known uses and disposals, and the result is that EPA is overlooking exposures in the real world. This approach is both contrary to law and arbitrary and capricious, as explained *infra* at Part I.D.

iv) *The legislative history does not justify or even lend support to EPA's approach.*

To justify its new position, EPA has emphasized the "legislative history" (p.11). But the legislative history, read as a whole, does not support EPA's approach. In the risk evaluation rule, EPA claims that the "legislative history of the amended TSCA *** explicitly states that the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation." 40 Fed. Reg. at 33,728 (citing 114 Cong. Rec. S3519-20 (daily ed. June 7, 2016) (statement of Sen. Vitter)). EPA relies on a floor

statement from a single Senator, which is one of the least illuminating forms of legislative history. EPA ignores that the rest of the legislative history reveals that other Senators thought that the statutory language would require EPA to consider all conditions of use in risk evaluations under the Lautenberg Act. Four principal Democratic negotiators of the legislation submitted a statement to the record that: "[t]he definition of 'conditions of use' described above plainly covers all uses of a chemical substance." 114 Cong. Rec. S3516 (daily ed. June 7, 2016). Similarly, when explaining why the bill expressly "grandfathered" in prior risk assessments (such as for Methylene Chloride), these negotiators explained that the provision was necessary because those "risk assessments for these chemicals were not conducted across all conditions of use." *Id.* at S3519. This explanation clearly reflects that *future* risk evaluations under TSCA would have to be conducted "across all conditions of use."

Unlike the text and structure of TSCA, the legislative history is somewhat ambiguous at points, although, if anything, it supports the position that EPA must consider "all conditions of use" since more Senators expressed that view and they did so in a formal statement.

B. Conditions of use expressly include certain so-called legacy uses and associated disposals.

In each of the scopes EPA stated that it *will* exclude so-called "legacy uses" and "associated disposal," (p.12) and EPA appears to rely on its reasoning from the risk evaluation rule. 82 Fed. Reg. at 33,729-30. EPA has asserted that no statutory text addresses this issue, and EPA stated that the use of the phrase "to be" in the definition of "conditions of use" implies a prospective application. 82 Fed. Reg. at 33,730; *see* 15 U.S.C. § 2602(4) (defining conditions of use to "mean[] the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen *to be* manufactured, processed, distributed in commerce, used, or disposed of") (emphasis added). EPA also (inaccurately) asserted that it did "not have an effective tool to address risks found to arise from uses in consumer settings if there" is no on-going manufacture, processing, or distribution. 82 Fed. Reg. at 33,730. But none of this reasoning survives scrutiny.

EPA's argument based on tense clearly does not apply to the legacy uses and associated disposals. If a chemical substance is present in a product or material that an industrial, commercial, or residential consumer is still using, then the substance is known "to be" used in that circumstance. Similarly, if a substance has not been disposed of yet, its disposal is in the future and reasonably foreseeable. As a result, these "legacy uses" and "associated disposal[s]" fall squarely within TSCA's definition of "conditions of use," which includes the "circumstances *** under which a chemical substance is *** known *** to be *** used, or disposed of." 15 U.S.C. § 2602(4). EPA has presented no textual basis for treating the first three participles in the list in this definition (manufactured, processed, and distributed in commerce) differently than the last two participles (used and disposed of).

EPA's theory that § 6 focuses on the "continuing flow of chemical substances" in "their lifecycles" (p.12) completely ignores that the use and disposal of a chemical is *part* of the lifecycle of a chemical, as defined by Congress in TSCA. Indeed, chemicals that are still in use are still "distributed in commerce" as that term is defined in TSCA. 15 U.S.C. § 2602(5). In the final risk evaluation rule, EPA stated that it

"believes the statute is better interpreted to focus on the prospective flow of the chemical substance," 80 Fed. Reg. at 33,730, but Congress expressly covered substances *after* their introduction into commerce as well.

EPA also justified its decision to ignore legacy uses by claiming it lacks tools to address risks from uses in consumer settings if there is no on-going commercial manufacture, processing, or distribution. 80 Fed. Reg. at 33,730. But TSCA § 6(a) expressly provides EPA with authorities that could manage some of these risks, even if it does not provide as broad authority as it does over manufacturers and processors. *See* 15 U.S.C. § 2605(a). For example, at risk management, EPA may impose "[a] requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture." *Id.* § 2605(a)(5). For example, EPA could ban the sale or future use of products containing a chemical even if that chemical is no longer in production in the United States, or EPA could require that such items be labeled. EPA may also impose "[a] requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or *by any other person* who uses, or disposes of, it for commercial purposes." *Id.* § 2605(a)(6)(A) (emphasis added).

In any event, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Indeed, in order to assess real-world risks of a chemical using the best available science, EPA needs to consider even those exposures over which it has limited or shared control. This approach is particularly appropriate given TSCA § 9's referral provisions.

C. The text and overall structure of TSCA makes it clear that EPA has to analyze uses, even if they have been assessed by another agency or are within another agency's jurisdiction.

EPA also stated that it may "exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risk" (p.12). But EPA provides no textual basis for ignoring those uses, which are often "circumstances *** under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Nothing in the risk evaluation provision or definition of conditions of use authorizes EPA to ignore conditions of use because of other agencies' jurisdiction over chemical substances. And several other provisions of TSCA indicate that Congress intended for EPA to consider such exposures, except to the extent Congress explicitly provided otherwise.

First, TSCA § 9(a) provides a detailed procedural mechanism for EPA under certain circumstances to request for another federal agency to address an unreasonable risk arising from a chemical substance that EPA has identified. 15 U.S.C. § 2608(a). This request then triggers a number of duties for both EPA and the other agency, requiring one of the two agencies to take action to address the risk. Thus Congress intended for EPA to prepare risk evaluations analyzing uses that might be addressed by another agency, and Congress created a substantive and procedural mechanism to resolve overlapping jurisdiction only *after* completing the risk evaluation. If EPA could just ignore risks arising from

conditions of use that fall within other agencies' jurisdiction, or if Congress meant for EPA to defer to those agencies' current regulatory approach to those chemicals at the outset before conducting a risk evaluation, then EPA might never make the finding that triggers the § 9(a) process. Here again, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Given that Congress expressly addressed the issue of overlapping regulatory jurisdictions in TSCA § 9, EPA cannot avoid those procedures by simply ignoring uses that fall within another agency's jurisdiction. Furthermore, EPA is expressly required to evaluate exposures from combinations of activities, which it cannot do if it excludes conditions of use at the outset that have been evaluated or regulated by another agency, particularly when that risk management is not an outright ban.

Second, Congress expressly exempted certain regulated chemicals or uses of chemicals from EPA's authority when it defined "chemical substance" in TSCA § 3(2). 15 U.S.C. § 2602(2)(B). For example, "chemical substance" does not include certain materials as defined in the Atomic Energy Act of 1954. *See id.* § 2602(2)(B)(ii), (iv). Thus, when Congress intended for EPA not to regulate certain conditions of use because they were regulated under other specific federal statutes, Congress expressly excluded those conditions of use. That Congress chose a limited, specific set of exclusions indicates that Congress did not intend for EPA generally to ignore other conditions of use even where they fall under other federal regulatory schemes.

D. The scopes contain incoherent and arbitrary and capricious reasoning because of EPA's approach to conditions of use.

EPA's illegal approach to "conditions of use" leads it to put "blinders" on regarding certain uses, exposures, and risks. The result is "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to have considered "factors which Congress has not intended it to consider [and] entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. It also violates several provisions of TSCA § 26 because by ignoring uses, exposures, and related information, EPA will not be acting "consistent with the best available science," EPA will not base decisions on "on the weight of the scientific evidence," and EPA will not "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h), (*i*), (k). In addition, because EPA's distinction is a false one untethered to the information, EPA seems to treat certain conditions of use inconsistently throughout the documents.

For example, in the 1,4-dioxane scope, EPA states that it will not consider risks arising from 1,4-dioxane when it is present as a by-product or residual contaminant from the manufacture of other chemicals. *See* 1,4-Dioxane, Scope at p.21, Docket ID: EPA-HQ-OPPT-2016-0723. But EPA identifies numerous products that "potentially contain[] 1,4-dioxane as a residual contaminant, including paints, coatings, lacquers, ethylene glycol-based antifreeze coolants, spray polyurethane foam, household detergents, cosmetics/toiletries, textile dyes, pharmaceuticals, foods, agricultural and veterinary products," as well as "magnetic tape and adhesives." *Id.* These are known and reasonably foreseen conditions of use

leading to exposures to 1,4-dioxane, and EPA's decision to ignore them when analyzing whether this chemical presents an unreasonable risk is arbitrary and capricious. EPA's theory is that it cannot regulate these impurities until it analyzes ethoxylated chemicals (*id.* at 8), but EPA provides no reasoned legal theory for why it could not act to regulate these exposures after this risk evaluation. *Id.* Even more problematically, EPA staked out the position that "EPA may choose not to include a particular impurity within the scope of any risk evaluation." 82 Fed. Reg. at 33,730. So these exposures may never be analyzed.

In addition, EPA acknowledges that 1,4-dioxane is often used as an intermediate or a reactant and that "the 1,4-dioxane would react either fully *or to a lesser extent*. Following completion of the reaction, the produced substance *may or may not be purified further*, thus removing unreacted 1,4-dioxane (if any exists). Reacted 1,4-dioxane is *assumed* to be destroyed and is thus not expected to be released or cause potential worker exposures." *See* 1,4-Dioxane, Scope at p.56, Docket ID: EPA-HQ-OPPT-2016-0723 (emphases added). But EPA never acknowledges that the unreacted 1,4-dioxane could lead to exposure. And that document provides no explanation, documentation, or quantification supporting the underlying assumption that 1,4-dioxane is destroyed or reacted. Indeed, from the description, it seems clear that it often will not be destroyed. The assumption in the last quoted sentence is contrary to the statements made in the proceeding sentences.

EPA's scopes should indicate that it will assess the reasonably available information on hazards and exposures for the substances (see Section II below), and that information should inform EPA's evaluation of the risks associated with "the conditions of use." If there is a real-world exposure, then EPA should not ignore it.

II. EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA §§ 4 and 8 to obtain additional information.

TSCA orders EPA to consider "available" and "reasonably available" information in crafting a risk evaluation, 15 U.S.C. §§ 2605(b)(4)(F)(i), 2625(k), and under the new risk evaluation rule, EPA defined "[r]easonably available information" to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 C.F.R. § 702.33, promulgated at 82 Fed. Reg. 33,748 (July 20, 2017). Thus, under its own rule, EPA has to consider information that it "can reasonably generate, obtain, and synthesize."

Yet, the scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is *reasonably* available information.

A. Any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities.

EPA must promulgate reasonable regulations under § 8(d) and 8(a) to obtain information about hazards, exposures, and conditions of use for these ten chemicals; EPA should also exercise its authority under § 8(c) to obtain additional information. Consistent with TSCA § 8(a)(5), EPA can take steps to reduce unnecessary and duplicative reporting. Because TSCA requires EPA to produce robust risk evaluations that reflect "reasonably available" information, and information available under these authorities is "reasonably available" on its face, EPA must use these authorities to fulfill its duty. Moreover, these first ten risk evaluations are crucial to establishing the credibility of the TSCA program under the Lautenberg Act, and EPA can only establish that credibility by using its full authority to obtain "reasonably available information" on chemicals, as required by the law. Collecting this information is also necessary to fulfill EPA's duty to use the best available science under TSCA § 26.

TSCA § 8(d) allows EPA to "require any person who manufactures, processes, or distributes in commerce *** any chemical substance or mixture *** to submit to the Administrator—lists of health and safety studies: (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person; or (C) reasonably ascertainable by such person." 15 U.S.C. § 2607(d). EPA should issue § 8(d) rules for these ten chemicals. To obtain a complete picture, EPA should expressly require both manufacturers and processors to report on these chemicals under the § 8(d) rules. *See* 40 C.F.R. § 716.5(c).

EPA has previously issued such rules for some of these chemicals, but two decades have passed since the last of those rules sunsetted, so new, additional health and safety studies are almost certainly available. For example, the methylene chloride and asbestos reporting periods sunsetted in 1992, the HBCD reporting period sunsetted in 1995, and the perchloroethylene reporting period sunsetted in 1997. *See* 40 C.F.R. § 716.120. Given scientific advancement over the last two decades, issuing new rules calling in health and safety studies would likely provide EPA with additional valuable information to assess the hazards, exposures, and risks posed by these chemicals. It appears that EPA has never issued such rules for Carbon Tetrachloride, Trichloroethylene, Pigment Violet 29, 1-Bromopane, 1-4 Dioxane, and N-Methylpyrrolidone. *See* 40 C.F.R. § 716.120. Thus, issuing § 8(d) rules for those chemicals is even more important.

Notably, EPA's regulations correctly interpret "health and safety study" broadly to incorporate "[a]ny data that bear on the effects of a chemical substance on health or the environment." 40 C.F.R. § 716.3. These include numerous tests for health and environmental effects. *See id.* They also include monitoring data and other assessments of human and environmental exposures. *See id.* EPA should also review these studies upon receipt and request underlying data under 40 C.F.R. §§ 716.10(a)(4), 716.40(a). EPA should also separately request reporting on these chemicals when they are manufactured, processed, or distributed as an impurity, 40 C.F.R. § 716.20(a)(9), because impurities may be an important source of exposure and thus risk, as explained above.

Under TSCA § 8(a), EPA may require manufacturers and processors to provide extensive information. *See* 15 U.S.C. § 2607(a)(2). EPA "shall, to the extent feasible" "not require reporting which is unnecessary or duplicative" and also "apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title." *Id.* § 2607(a)(5). To avoid duplication, EPA need not request reporting on information EPA has already obtained through other recent submissions such as through the Chemical Data Reporting (CDR) process. *See* 40 C.F.R. Part 711. But the CDR process does not require manufacturers and processors to provide all information that EPA can reasonably obtain under TSCA § 8(a) which is relevant to the risk evaluations. For example, EPA should require reporting of: "[a]ll existing information concerning the environmental and health effects of" each chemical; "the byproducts resulting from the manufacture, processing, use, or disposal of each" chemical; more detailed information about exposures to these chemicals, including the duration, frequency, and timing of exposures; and additional information about disposal. *See* 15 U.S.C. § 2607(a)(2). In particular, EPA can require submission of any data available on releases or exposures in the workplace and environment, and those data would be crucially important to an accurate risk evaluation. To decrease the burden on industry, EPA should pursue both rulemakings simultaneously, and EPA can provide that when information is submitted under one rule, the same information need not be submitted under the other. But EPA should use both authorities to ensure that it does not miss any information that may fall within one authority but not the other.

In addition, EPA should rely on its request authority under TSCA § 8(c). Under TSCA § 8(c), "[a]ny person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture." 15 U.S.C. § 2607(c). EPA promulgated rules governing this recordkeeping requirement at 40 C.F.R. Part 717. The rules apply to most manufacturers and many processors. 40 C.F.R. § 717.5. Manufacturers and processors must maintain records of many types of allegations, as detailed in 40 C.F.R. §§ 717.5 and 717.10. The regulation defines "significant adverse reactions" to include, but not be limited to, many specific types of harm that are highly relevant to the ultimate question presented in a risk evaluation: "whether a chemical substance presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(b)(4)(A). Firms must maintain these records for 30 or 5 years, depending on the circumstances. 40 C.F.R. § 717.15(d).

EPA should use its authority to request these records on alleged significant adverse reactions caused by the ten chemicals analyzed in the scope documents and add them to the administrative record for the relevant chemical. EPA can request records from manufacturers and processors that reported the chemicals in response to any § 8(a) and 8(d) rules or in response to CDR reporting. *Id.* § 717.17. EPA can request those records by letter. *Id.* § 717.17(b). Finally, EPA can also notify all people holding such records to provide them by a notice in the Federal Register. *Id.* These records may provide valuable information on hazards, exposures, and conditions of use, since the records may reveal not only significant adverse reactions but also information about the specific exposure and use that may have caused the reaction.

B. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps.

EPA should make robust use of its § 4 authority to fill any gaps in information. EDF recognizes that time constraints apply to these first ten chemicals and thus some types of testing may not be possible, but going forward, EPA needs to use its authority fully and do so in a timeframe that ensures it will have all of the information it needs to conduct risk evaluations.

As EPA moves forward on the first 10 risk evaluations, it should first clearly identify *all* significant information gaps on hazards or exposures. Based on its own regulation, EPA must then use its authority under TSCA § 4(a)(2) to require the development of new information to fill those gaps wherever possible. Information that EPA can generate under TSCA § 4(a)(2) is reasonably available under EPA's own regulation as "information that EPA *** can reasonably generate [and] obtain *** for use in risk evaluations." 40 C.F.R. § 702.33. Thus, EPA should identify such information gaps and then promptly require the conduct of all testing that can be done and still meet the statutory deadlines for the risk evaluations.

TSCA § 4(a)(2) provides that EPA "may, by rule, order, or consent agreement require the development of new information relating to a chemical substance *** if the Administrator determines that the information is necessary *** to perform a risk evaluation under section 6(b)." 15 U.S.C. § 2603(a)(2)(A)(i). Congress provided this additional testing authority allowing EPA to require testing or other data development efforts solely upon a determination "that the information is necessary *** to perform a risk evaluation under section 6(b)." *Id.* In light of deadlines, EPA can and should use its order authority and does not need to make the additional findings required for a rule under TSCA § 4(a)(1).

In places in these scopes, EPA seems to be going out of its way to avoid using its information authorities. For example, in numerous places in these scopes, with respect to exposure, EPA indicates that "[f]or conditions of use where data are limited or not available, [it will] review existing exposure models that may be applicable in estimating exposure levels" (p.43). This language suggests that EPA will simply default to models rather than use its authority to get needed information. In EDF's view, EPA should first use its authorities under TSCA §§ 8 and 4 to fill those information gaps, rather than rely on models to compensate for lack of information. This is not to say that exposure models do not have a role, but they are not a basis for avoiding the obligation to collect information.

Our review of the scopes indicates that there are significant gaps in the information. Where possible EPA needs to fill those gaps. When it is not possible, consistent with TSCA § 26, EPA needs to identify those gaps and characterize the uncertainty in the draft risk evaluations. To cite just one example, in the scope for Methylene Chloride EPA completely fails to mention an information gap earlier identified in the Work Plan. Specifically, the 2014 Work Plan Assessment for Methylene Chloride identified both developmental neurotoxicity and immunotoxicity from chronic exposure as important data gaps, impacting the selection of the point of departure:

> There is uncertainty about chronic exposure impacts on the nervous system function. The nervous system has been well studied and identified as very sensitive for acute effects. However, there is a paucity of data on chronic neurological impacts, especially developmental neurotoxicity. Likewise, there is limited information about immunotoxicity following chronic exposure to DCM. Existing hazard studies are not sufficient for dose response analysis to provide a lower point of departure than existing adverse findings in the liver from chronic exposures."

See Methylene Chloride: Paint Stripping Use, TSCA Work Plan Chemical Risk Assessment at p.115, https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf

C. If EPA already has relevant information, it is reasonably available and EPA should consider it.

The strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." *See, e.g.*, Asbestos literature at p.13. But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation *** is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available, EPA must review it.

In addition, much of this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. First, historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act. Second, the Lautenberg Act greatly increased the requirements companies must meet to assert CBI claims. For example, information only qualifies for protection if the submitter asserts *and* substantiates that it has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c). Thus, even if the information once merited protection, it may no longer be confidential under the standards of TSCA § 14. Third, as a general rule, TSCA § 14(b)(2) provides that health and safety studies and information from health and safety studies are not entitled to confidential treatment, so much of this information may not be confidential under that provision.

To fulfill its duties under TSCA, EPA must review this reasonably available information and identify that which is potentially relevant to the risk evaluations. Where information is relevant, EPA should also consider whether the information meets the strict requirements for nondisclosure under TSCA § 14. If not, EPA should add it to the administrative record for review by the public. Whether or not it meets those requirements, EPA should then determine whether and how to consider the information in evaluating these chemicals. Notably, TSCA § 26(j) requires that, "subject to section 14," EPA "shall make

available to the public *** a list of the studies considered by [EPA] in carrying out each such risk evaluation, along with the results of those studies." 15 U.S.C. § 2625(j).

D. When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information.

In the literature searches, EPA sometimes states that it relied on recent assessments, and then only performed research for dates beyond those assessments. *See, e.g.*, 1,4-Dioxane, Strategy for Conducting Literature Searches for 1,4-Dioxane: Supp. File for the TSCA Scope at p.7, 9-10, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0047. EPA needs to provide a short analysis presenting its review of the prior analysis to ensure it adequately captured and addressed all reasonably available information as of the date of its publication, particularly given the expanded obligations under the Lautenberg Act. If EPA finds it was not adequate, then EPA should broaden its literature search.

III. EPA needs to take additional steps to ensure both the completeness and accuracy of the information it relies upon.

As explained above, EPA should rely on its authorities under TSCA §§ 8 and 4 to obtain all reasonably available information. Those authorities include a number of measures to ensure the accuracy and completeness of the data relied upon. To the extent EPA relies on voluntarily submitted information, EPA needs to take additional steps to ensure the accuracy and completeness of the information. Otherwise, EPA will violate TSCA § 26 by failing to make decisions "in a manner consistent with the best available science." 15 U.S.C. § 2625(h)

A. EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals.

EPA has requested in each of the scopes that industry and other stakeholders provide information. While this voluntary request was a reasonable first step towards obtaining the necessary information, EPA has failed to provide any account for how this voluntary approach to collecting information will result in EPA obtaining all "reasonably available" information as EPA has defined that term. There are several obvious problems and limitations with this voluntary approach which EPA has not even acknowledged, much less addressed.

First, a voluntary call is much less likely to produce all of the necessary information than rules mandating that affected parties provide the requested information. If manufacturers and processors are legally required to provide the information, that legal obligation provides a strong incentive for them to collect and submit all relevant information. Absent that incentive, some companies may choose to focus time and attention on other matters. Indeed, the burdens (whether one considers them heavy or light) of collecting and submitting information counsel in favor of issuing mandatory rules. *If* the process of

collecting and submitting the information is not onerous or difficult, then using rules to require the submission of the information will do little if any harm to the regulated industry, and use of rules will ensure EPA has a complete picture and increase credibility. Alternatively, to the extent that the process is onerous or difficult, it is even more important that EPA *require* the submission of the information, because otherwise those burdens will likely discourage stakeholders with relevant information from collecting and submitting the information.

Second, EPA has provided no empirical evidence establishing that this voluntary approach will result in EPA obtaining all "reasonably available" information. Unless EPA has some empirical basis for stating that the voluntary approach will allow EPA to obtain all reasonably available information that it can obtain under its legal authorities, EPA must rely on its existing authorities to obtain a complete set of information.

Indeed, EPA's prior experience with voluntary reporting provides strong evidence that a voluntary approach is unlikely to provide complete and accurate data. For example, an EPA advisory committee called for the development of nanomaterial reporting rules in 2005, but EPA instead spent several years developing and carrying out a voluntary reporting program, the Nanoscale Materials Stewardship Program (NMSP). This voluntary reporting program produced minimal information as revealed by EPA's 2009 interim report on the NMSP. Nanoscale Materials Stewardship Program, Interim Report, OPPT (Jan. 2009), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0003. "[I]n the report EPA estimated that companies provided information on only about 10 percent of the chemical substances manufactured at the nanoscale that may be commercially available in 2009." 80 Fed. Reg. 18,330, 18,334 (April 6, 2015). In 2017, over a decade after the data need was identified, EPA finally finalized a § 8(a) reporting rule to acquire the data. 82 Fed. Reg. 3641 (Jan. 12, 2017). Given the past failures of voluntary approaches, EPA should not rely on them here.

Third, manufacturers and processors of these chemicals have a vested interest in EPA finding that the chemicals do not present an unreasonable risk. A no-unreasonable-risk finding reduces the likelihood of government regulation, including potential restrictions on risky chemicals, and it may reduce any stigma they may otherwise face in the marketplace. The financial costs of regulation may ultimately be very high for some specific firms and individuals, and even if not, many firms and individuals may *believe* that the costs of regulation will be high. These companies have a "financial interest" in the outcome of these proceedings, and they are not impartial. *See, e.g.*, 28 U.S.C. § 455(b)(4) (requiring Judges to disqualify themselves in proceedings where they have a financial interest). Because of this reality and appearance of partiality, relying solely on voluntary measures decreases the credibility of these risk evaluations.

Relying solely on voluntary presentation of information raises the concern that the companies or trade associations may present an incomplete or skewed picture. Companies and trade associations may choose to "cherry pick" information and provide only the information that paints their chemicals in favorable light. They may provide only summaries of information that reflect conscious and subconscious judgment calls that result in unduly favorable conclusions; and without access to the full information neither EPA nor the public can independently assess such conclusions. They may choose

not to review records robustly when the review may disclose unfavorable information. They may seek to put their best foot forward and describe the ideal scenario of use and safety measures. Or, if they have unfavorable information, they may choose not to provide any information at all and simply not participate in these proceedings.

To be sure, members of the regulated community are crucial sources of information about their chemicals' uses, hazards, and exposures, but EPA cannot simply assume that they will voluntarily disclose unfavorable or complete information about their practices and products. *See* THE FEDERALIST NO. 51 (James Madison) ("If men were angels, no government would be necessary. *** [E]xperience has taught mankind the necessity of auxiliary precautions."); *Williams v. Pennsylvania*, 136 S. Ct. 1899, 1905-06 (2016) ("Bias is easy to attribute to others and difficult to discern in oneself. *** This objective risk of bias is reflected in the due process maxim that 'no man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome.'"). Here, manufacturers and processors obviously have an interest in the outcome, and EPA must craft its procedures and approaches with that reality in mind. Requiring the submission of information is the safest approach to ensuring that these parties provide all relevant information, and that is in turn crucial to establishing and demonstrating the credibility of this process.

If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information. First, EPA can require that certain information and underlying information be provided in full, which ensures completeness. In addition, a § 8(d) rule requires that people engage in an adequate search of records. 40 C.F.R. § 716.25. Second, submitters must file certification statements by authorized officials that certify that the submitted information has been submitted in compliance with the requirements of this process. *See, e.g.*, 40 C.F.R. § 711.15(b)(1). Third, submitters often must retain records of required submissions for a period of five years, and the retention of records can help encourage accurate reporting since those records would be available should a submission latter be investigated. *See, e.g.*, 40 C.F.R. § 711.25. None of these features apply to the voluntary requests for information EPA has indicated it is relying on.

In addition, as EDF has explained in prior comments, there are numerous reasons that it is important that the public have access to full studies and the underlying information, not simply robust or other study summaries. *See, e.g.*, EDF Comments on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act, Comment at p.37, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074. Without access to full studies, the public will be challenged or unable to assess and comment on the quality of the studies used by the agency. *Id.* EDF reincorporates and reiterates the numerous points made in support of public access to the full studies here. *Id.* These points also support the importance of EPA obtaining the full studies.

B. For voluntary submissions, EPA should take additional steps to ensure completeness and accuracy and to vet information based on underlying data.

To the extent it relies on voluntary submissions, EPA can and should take additional steps to better ensure that the voluntary information it receives is accurate and complete. EPA would need to develop a far more rigorous and structured process than it currently has. For example, EPA's submission process does not appear to require anyone to certify that the information in their comments is accurate or complete to the best of their knowledge. EPA should consider approaches for vetting statements and assertions, particularly when made by entities with a financial interest in the outcome of these risk evaluations.

EPA should also request that submitters always provide full studies, as well as underlying data whenever reasonably available or obtainable. Setting aside concerns about partiality, EPA needs the underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular submission.

In addition, EPA should seek input directly from workers for manufacturers and processors, providing them an easy method to submit information on workplace practices and conditions independently from management. EPA needs to take steps to allow workers to provide input in a manner that reduces the risks of any potential retaliation from management.

To give a few specific examples from the scopes:

In the Perchloroethylene scope (also known as tetrachloroethylene or PCE), EPA cites the Vinyl Institute's comments for the fact it can be a residual or byproduct in the manufacture of other chemicals. *See* Perchloroethylene, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0732 (citing comment at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0013). That comment, in turn, contains a table claiming to summarize the approximate concentrations of Perchloroethylene in light and heavy end liquid intermediate streams yielded in the EDC/VCM process for manufacturing each of four chlorinated organic substances. The comment states that there is no residual Perchloroethylene in light liquid ends and 1.1% by typical weight in heavy liquid ends. But the comment does not provide or cite any underlying data supporting these findings. When commenters provide summary statements along these lines, EPA should give them little weight unless it also receives the underlying data to ensure that the reported results or conclusions drawn accurately reflect real-world conditions and to assess the level of certainty and scope of applicability that EPA can attribute to the results or conclusions. This point holds for all of the percentages set forth in that table, including those for the other three products.

Similar concerns arise for many of the other scopes. For example, in the Carbon Tetrachloride scope, EPA states that: "there are public comments, EPA-HQ-OPPT-2016-0733-0005 [3M] and EPA-HQ-OPPT-2016-0733-0017 [ACC], stating that carbon tetrachloride may be present in a limited number of industrial products with chlorinated ingredients at a concentration of less than 0.003% by weight." Carbon Tetrachloride, Scope at p.20, Docket ID: EPA-HQ-OPPT-2016-0733. But upon examining those

comments, they do not provide any of the underlying data or enough information to assess accuracy of the statement or the level of uncertainty that should apply to the results. The ACC comment is particularly difficult to assess. It involves multiple levels of hearsay, with ACC reporting statements that companies reported to it. Some of those companies acknowledge they are also relying on hearsay from suppliers and have not taken steps to confirm these concentrations. Those suppliers might also be relying on hearsay; it is simply not clear what the bases are for some of these values. Hearsay is, of course, particularly problematic when the statement serves the interest of the person submitting the evidence. *See, e.g.*, FED. R. EVID. P. 804(b)(5) (exception for statements against interest). As such, these concentrations arguably provide at best a "lower bound" estimate; they are not sufficient in terms of establishing that the actual concentrations are not higher. While no formal hearsay rule applies to these administrative proceedings and the hearsay evidentiary rule generally has limited applicability to technical studies and business records, it is relevant to the weight EPA should give these reported values given these circumstances. ACC does not disclose the companies providing the information, making it impossible for EPA to independently address these kinds of concerns. In addition, ACC's comment often fails to provide any clarity or detail as to how the concentrations were measured or assessed, much less provide the data underlying these claimed concentrations. The ACC comment asserts concentrations for 1,4-Dioxane, Pigment Violet 29, N-Methylpyrrolidone (NMP), Methylene Chloride (DCM), Carbon Tetrachloride, and HBCD, but for most of these concentrations, it is impossible for EPA or the public to assess whether they are accurate. For some of these concentrations, the comment states that Safety Data Sheets and Technical Data Sheets are provided with the comments, but EDF did not find any attachments with the comment containing those materials. In sum, EPA needs to scrutinize these voluntary submissions carefully and ensure access to the underlying information, which is necessary to assess the accuracy of the statements therein.

In the asbestos scoping document, EPA acknowledged that the analysis of the Chlor-Alkali industry was "primarily based on information provided by either the chlor-alkali industry or [the American Chemistry Council] and is meant to represent typical practices." *See* Asbestos, Scope at p.54, Docket ID: EPA-HQ-OPPT-2016-0736. EPA correctly recognized that EPA should "further evaluate how representative the processes witnessed at these two facilities are of processes at other plants." *Id.* at 23. EPA should take measures to ensure that its process will in fact accurately assess the full range of existing practices, relying on independent data where possible. Where independent data are unavailable, EPA should reach out to workers directly to better determine actual practices. Even when companies have good practices on paper, those practices may not be the reality on the ground.

EPA also needs to carefully scrutinize statements to ensure it correctly interprets them.

IV. These scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations.

Broadly viewed, the scopes do not meet several of the statutory requirements of TSCA. TSCA § 6(b)(4)(D) requires that EPA "shall, not later than 6 months after the initiation of a risk evaluation,

publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D). These scopes do not fully satisfy these requirements. Some aspects are plainly illegal under *any* interpretation of the statute, for the reasons given above, such as the statement that "EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11).[1] But many other aspects, while problematic, can be resolved by EPA in the next step: its development of problem formulations.

It is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. EDF believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified. With respect to susceptible populations, EPA should consider workers and, in most cases, pregnant women and children, to be potentially exposed or susceptible subpopulations. We identify below a number of specific examples where EPA's scopes are unclear and merit further study.

A. 1,4-Dioxane

EPA states: "EPA evaluated the weight of the evidence for cancer in humans and animals and concluded that 1,4-dioxane is 'likely to be carcinogenic to humans' based on evidence of carcinogenicity in several 2-year bioassays." 1,4-Dioxane, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0723. However, certain language in this section suggests that EPA may not include cancer as a hazard endpoint in the risk evaluation.

Indeed, EPA almost seems to suggest that inconclusive evidence regarding the "mode of action by which 1,4-dioxane produces liver, nasal, peritoneal (mesotheliomas) and mammary gland tumors" might form a basis for disregarding the evidence of such hazards. *Id.* at 35. As a general matter, EPA should not exclude observed hazards simply because the underlying MOA is not fully delineated or understood, doing so would significantly and inappropriately jeopardize the robustness and health-protections of the risk evaluation. If there is evidence of hazard, EPA should include it in the risk evaluation, even if the precise mode of action is not yet understood.

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[1] As explained above, EPA puts too much weight on a floor statement from a single Senator, David Vitter. But even Senator Vitter stated that EPA must consider all conditions of use identified in the scope. *See* 114 Cong. Rec. S3520 (daily ed. June 7, 2016) (statement of Sen. Vitter). Despite that statement, the scoping documents all state that "during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11). Thus, EPA is inconsistent in how much weight it gives to Senator Vitter's statements, and EPA's current interpretation appears to contradict the views expressed throughout the legislative history by every single legislator. If EPA excluded uses identified in the scope, such as uses in the chlor-alkali industry (e.g., pp.20, 23-24), then EPA will be acting contrary to Senator Vitter's statement.

B. Perchloroethylene

The scope for Perchloroethylene states that "EPA expects to consider hazards identified in the recent assessment by the EPA Integrated Risk Information System (IRIS) Program: neurotoxicity, kidney toxicity, liver toxicity, developmental and reproductive toxicity and cancer. Support for an association with immune and blood effects was less well characterized." Perchloroethylene, Scope at p.11, Docket ID: EPA-HQ-OPPT-2016-0732. It is unclear from the scope whether EPA intends to include immune and blood effects in particular.

C. Trichloroethylene (TCE)

In the scope for TCE, EPA suggests that TCE's use as a spot remover will not be analyzed because it was previously analyzed in a risk evaluation. TCE, Scope at p.25, Docket ID: EPA-HQ-OPPT-2016-0737. That approach may be reasonable if EPA finalizes its proposed ban on this use of TCE to address those risks, as discussed more below. But that approach only applies to those spot remover uses that have previously been analyzed, specifically commercial dry cleaning facilities. This risk evaluation needs to consider TCE's use as a consumer spot remover. Those uses have not been analyzed in-depth, and the 2014 work plan assessment recognized that some such products may contain TCE as a main ingredient. *See* Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses, TSCA Work Plan Chemical Risk Assessment at p.52, https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

D. N-Methylpyrrolidone (NMP)

The NMP scope has numerous inconsistencies with respect to its identification of the endpoints to be assessed. EPA begins by acknowledging that a "number of human health hazards have been identified for NMP including adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems." N-Methylpyrrolidone, Scope at p.36, Docket ID: EPA-HQ-OPPT-2016-0743. EPA also states that: "EPA expects to consider all potential hazards associated with NMP." *Id.* EDF completely agrees with that approach. However, the description under section 2.42 Human Health Hazards indicates that EPA intends to focus on a narrower set of hazards (acute toxicity and reproductive/developmental toxicity), and provides no justification or even explanation for excluding some of the hazards that it previously identified.

E. Potentially exposed or susceptible subpopulations

EPA also does not identify pregnant women, women of childbearing age, or the developing fetus as potential exposed or susceptible subpopulations for either N-Methylpyrrolidone (NMP) [NMP, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0743] or TCE [TCE, Scope at pp.37-38, Docket ID: EPA-HQ-OPPT-2016-0737], despite the fact that EPA's previous risk assessments on these two chemicals identify women of childbearing age and the developing fetus as a primary susceptible population (in addition to workers). EPA's failure to identify these populations in the scopes is both contrary to law and an abuse of discretion. TSCA § 3(12) defines "potentially exposed or susceptible subpopulation" to include "a

group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance *** , such as infants, children [or] pregnant women." 15 US.C. § 2602(12). Here, EPA has previously found that "women of childbearing age" are at greater risk of adverse health effects from these chemicals. 82 Fed. Reg. 7432, 7434 (Jan. 19, 2017); 82 Fed. Reg. 7464, 7467 (Jan. 19, 2017).

Furthermore, TSCA requires that EPA identify "the potentially exposed or susceptible subpopulations the Administrator expects to consider" in the scopes. 15 US.C. § 2605(b)(4)(D). While EPA has considered those at greater risk due to *increased exposure* in the scopes to some extent, the agency appears to defer the process of identifying populations with *greater susceptibility* to the problem formulation or risk evaluation stage: "In developing the hazard assessment, EPA will also evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s)." *See, e.g.*, NMP, Scope at pp.36-37, Docket ID: EPA-HQ-OPPT-2016-0743; 1,4-Dioxane, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0723.

V. EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures.

The scoping documents generally acknowledge the need to analyze activities related to a chemical's distribution, but EPA will need to analyze these exposures more robustly than the scopes currently reflect. *See, e.g.*, 1,4-Dioxane, Scope at p.22, Docket ID: Docket ID: EPA-HQ-OPPT-2016-0723.

The scoping documents give little, if any, attention to potential releases and exposures resulting from accidental releases. EDF does not suggest that EPA needs to consider every possible scenario, but the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks. For example, as and after Hurricane Harvey passed through Houston, over 40 sites released toxic chemicals into the environment. *See, e.g.*, More Than 40 Sites Released Hazardous Pollutants Because of Hurricane Harvey, https://www.nytimes.com/interactive/2017/09/08/us/houston-hurricane-harvey-harzardous-chemicals.html?_r=0. Given the *known* accidental releases, the huge number of petrochemical plants and refineries in the Houston area, and the likelihood that flooding there may become more common in light of climate change, such events are clearly reasonably foreseen and hence EPA needs to give more consideration to the potential for accidental releases.

VI. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures.

Language used in the scopes suggests that EPA may inaccurately assume that people comply with all warning labels and always use personal protective equipment (PPE). EDF strongly urges EPA to consider real-world exposures reflecting the reality of the sometimes low-compliance with or non-existence of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by

either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). And absent empirical evidence establishing the extent to which people are using these measures, EPA should assume that they may not be. Indeed, EPA's need for accurate information about actual compliance is another reason to rely on its authorities under TSCA § 8 to mandate that manufacturers and processors provide that information. In addition, it bears noting that reliance on PPE as a primary measure to protect workers is counter to OSHA's Industrial Hygiene Hierarchy of Controls (HOC), a long-standing principle that prioritizes measures to eliminate or reduce the presence of a hazard in occupational settings (e.g., substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves, such as through reliance on PPE and warning labels. The HOC exemplifies the best available science for creating safe, healthful workplace environments.

As an example of a problematic reference to PPE in the scopes, in the asbestos scope, EPA stated that "[d]ermal exposure is unlikely due to glove use in the workplace." Asbestos, Scope at p.37, Docket ID: EPA-HQ-OPPT-2016-0736. But EPA cites no evidence supporting this assumption. While gloves may be used in many workplaces, EPA needs to provide evidence of the extent of such use. Among other things, EPA correctly noted earlier that "certain conditions of use, such as a mechanic changing asbestos-containing brakes, may also result in dermal exposure." *Id.* at 35. Is there any evidence that all or even most mechanics wear gloves when changing brakes? Indeed, EPA should identify mechanics as a relevant potentially exposed or susceptible subpopulation based on their exposure to brakes.

In comments EDF has submitted in these dockets, EDF previously commented on the serious limitations of labeling and PPE, as well as the importance of adherence to the hierarchy of controls to limit workplace exposures. *See, e.g.*, EDF comments at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0046, March 15, 2017; and at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052, November 21, 2016. EDF reincorporates and reiterates the points made in those comments here.

VII. EPA's decision not to examine uses addressed by its planned § 6(a) rules governing certain uses of TCE, DCM, and NMP is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses.

For Trichloroethylene (TCE), Methylene Chloride (DCM), and N-Methylpyrrolidone (NMP), EPA states that conditions of use previously examined will not be re-evaluated. TCE, Scope at p.9, Docket ID: EPA-HQ-OPPT-2016-0737; DCM, Scope at p.29, Docket ID: EPA-HQ-OPPT-2016-0742 ("This includes uses assessed in the U.S. EPA (2014a) risk assessment and therefore those uses are out of scope for the risk evaluation."); NMP, Scope at pp.20, 28, Docket ID: EPA-HQ-OPPT-2016-0743 ("This includes uses assessed in the previous EPA risk assessment (U.S. EPA, 2015) and therefore those uses are out of scope for the risk evaluation."). EPA has previously found these uses even by themselves present unreasonable risks to human health. In addition, these uses have the potential to increase the total

exposure of people to these chemicals. As a result, EPA can only reasonably exclude these uses if it finalizes the proposed rules to ban these uses. EDF strongly supports those bans for the reasons it articulated in its prior comments.

If EPA does not finalize these bans, then excluding these uses is both contrary to law and arbitrary and capricious. By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses *unless* EPA has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals.

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EDF appreciates the opportunity to provide comments and EPA's consideration of them.

Environmental Defense Fund Comments on

Ten Scopes under the Toxic Substances Control Act

Docket IDs: EPA-HQ-OPPT-2016-0725 (Pigment Violet 29), EPA-HQ-OPPT-2016-0723 (1-4, Dioxane), EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene), EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride), EPA-HQ-OPPT-2016-0735 (HBCD), EPA-HQ-OPPT-2016-0736 (Asbestos), EPA-HQ-OPPT-2016-0737 (Trichloroethylene), EPA-HQ-OPPT-2016-0741 (1-Bromopropane), EPA-HQ-OPPT-2016-0742 (Methylene Chloride), and EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone)

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The Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on the scopes for the risk evaluations for the first ten chemicals being evaluated under section 6(b)(4) of the Toxic Substances Control Act (TSCA) as amended by the Lautenberg Act, enacted on June 22, 2016.

In addition to specific comments on each chemical, EDF is providing broad comments addressing the scopes of risk evaluations for the first 10 chemicals as well as others in the future. While our comments are broadly applicable to all of the scope documents, we include examples from specific scopes to illustrate flaws and limitations.

As explained below, these scopes deviate from certain requirements of the law and in places are too unclear and vague or ambiguous to allow us to provide definitive comments. EDF recognizes that EPA was working under tight deadlines in producing these scopes – a problem it further exacerbated by EPA's decision to make major, late changes to the risk evaluation rule. EPA should take advantage of the upcoming problem formulation stage to address the many problems we identify below, and to more clearly and transparently explain its plans for these risk evaluations.

Before discussing the merits of the scoping documents, EDF provides the following clarification about its citation approach. Each scoping document contains largely identical, boilerplate language providing the agency's overall legal approach to "conditions of use" as well as its approaches on some other issues. Indeed, each document includes the same typos or misquotes of the underlying law. For ease of reference and to reduce excessive citations, EDF quotes from the asbestos scoping document and provides simply the page number when addressing these broader legal problems that are present in each scoping document. These comments equally apply to all scoping documents since they all contain

this same language; the only difference is page number. When EDF is specifically quoting another scoping document, we provide a citation clarifying that point.

Contents:

I. TSCA requires EPA to analyze whether a chemical substance, as a whole, presents an unreasonable risk, and EPA does not have discretion to ignore conditions of use.

EPA's scoping documents (pp.11-13) state that EPA has determined that "certain activities may not generally be considered to be conditions of use" (p.11) and also that EPA may "exclude certain activities that EPA has determined to be conditions of use" (p.12). EPA's approach asserts that EPA is allowed to ignore numerous circumstances falling within the statutory definition of "conditions of use" and is contrary to law. For the current set of chemicals under review, EPA may well be ignoring circumstances leading to ongoing exposures, and as a result, will fail to evaluate the risks the chemicals actually pose to human health and the environment.

TSCA's language and structure unambiguously foreclose EPA's interpretation. EPA's decision to disregard certain uses and exposures is also "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to consider "factors which Congress has not intended it to consider [and] entirely fail[] to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, as the scoping documents themselves reveal, this approach leads to irrational and arbitrary applications. Instead, EPA should be guided by the statutory language and consider all of those circumstances falling within the definition of "conditions of use." EPA should evaluate all of the circumstances revealed by the evidence of use and exposure, not ignore evidence because of self-imposed blinders.

A. The plain text, overall structure, purpose, and legislative history of TSCA indicate that EPA has to determine whether a chemical substance presents an unreasonable risk comprehensively, under all of its conditions of use.

i) *The plain text requires EPA to consider all conditions of use.*

Statutory interpretation should begin, as always, with the language of the statute. The plain language of both the risk evaluation provision and the definition of conditions of use support the interpretation that EPA must consider all circumstances falling within the statutory definition of "conditions of use." The main risk evaluation provision, TSCA § 6(b)(4)(A), directs that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). Inserting the statutory definition of conditions of use, this provision provides that EPA "shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk *** under "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* §§ 2605(b)(4)(A), 2602(4). Thus, EPA has to analyze the risks of a substance under the circumstances described in the definition of "conditions of use," and no qualifying language allows EPA to exclude circumstances within that definition. The clause "as determined by the Administrator" calls for a factual finding or determination to be made by EPA. The relevant dictionary definition of "determine" is to "ascertain or establish exactly, typically as a result of research or calculation." OXFORD

AMERICAN DICTIONARY 474 (3d ed. 2010). While EPA may exercise reasonable judgment when interpreting "reasonably foreseen," nothing in this language grants EPA discretion to *ignore* factual circumstances that fall within the definition of "conditions of use." Indeed, statutes often direct agencies "to determine" things or make "determinations," and it is understood that the agency must make the finding required by the statutory language.

EPA's position that it can ignore known and foreseeable uses violates the text of the law. In the scoping documents, EPA asserts that it may ignore "legacy uses" and "associated disposals," impurities, alleged "de minimis" exposures, intermediates, conditions of use within closed systems, and conditions of use that have been analyzed by another regulatory agency (p.12). But "conditions of use" expressly includes "the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen to be to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). And every one of those circumstances is a "known" or "reasonably foreseen" "manufacture", "process[ing]," "use," or "disposal of" a chemical substance. Congress expressly chose to define "conditions of use" broadly to include not only "intended," but also "known" or "reasonably foreseen" manufacture, processing, distribution, use, and disposal. 15 U.S.C. § 2602(4). Disregarding chemical substances present as impurities or byproducts in the scoping documents, for example, because they are not "intended" essentially reads the other two scenarios out of the statute. Similarly, all the other identified conditions of use are also "intended, known, or reasonably foreseen." For example, EPA's scope suggests that 90% of the domestic production of Pigment Violet 29 "is processed as a site-limited intermediate." Pigment Violet 29, Scope at p.19, Docket ID: EPA-HQ-OPPT-2016-0725. It would absurd to ignore these intermediate uses when analyzing this chemical; doing so will lead to a truncated and incomplete analysis. Similarly the decision to exclude 1,4-dioxane's presence in numerous consumer, commercial, and industrial products as a byproduct of ethoxylation is entirely inappropriate, and will result in deficient and erroneous evaluation and determination of the chemical substance's risks. The same points can be made for many of the other chemicals used as intermediates or present as byproducts of chemical or product manufacture.

In contrast to the correct interpretation, EPA's new interpretation finds no support in the text. In the final risk evaluation rule (82 Fed. Reg. 33,726, 33,729 (July 20, 2017)), the only statutory textual basis for EPA's theory appears to be the "expects to consider" clause in the scope provision, TSCA § 6(b)(4)(D), requiring EPA to "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator *expects to consider*." 15 U.S.C. § 2605(b)(4)(D). But "expects to consider" does not mean "chooses to consider" or "prefers to consider." It is not the language of discretion; it is temporal language of anticipation or prediction. The dictionary definition of "to expect" is to "regard (something) as likely to happen." OXFORD AMERICAN DICTIONARY 609 (3d ed. 2010). This language indicates that, in the scope, EPA should describe what it anticipates studying, but it does not state that EPA has discretion to choose to ignore intended, known, or reasonably foreseen uses, hazards, or exposures. Moreover, the provision dictating what EPA must consider during a risk evaluation does not limit EPA's analysis to conditions of use identified in the scope. 15 U.S.C. § 2605(b)(4)(F). Indeed, EPA must consider all such conditions to fulfill its requirement that EPA account for the "likely duration, intensity, frequency, and

number of exposures under the conditions, where relevant." 15 U.S.C. 2605(b)(4)(F)(iv). Thus, the statutory language does not support EPA's assertion of discretion, including EPA's decision to limit its analyses to those factors identified in each scope. For example, under the rule of the last antecedent, the phrase "the Administrator expects to consider" does not even *modify* "conditions of use" or "hazards" or "exposures." Notably, EPA has so little regard for the statutory language that it repeatedly misquotes this language in significant ways.

Textually, EPA's argument also directly conflicts with TSCA § 26(k). 15 U.S.C. § 2625(k). TSCA § 26(k) requires EPA to "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." *Id.* Notably, this requirement does not include *any* conditional phrase that modifies "conditions of use." And Congress included this provision to ensure that EPA could not ignore "reasonably available" "information relating to a chemical substance or mixture"; the purpose of this provision is to compel EPA to consider all reasonably available information. It would undermine this directive if EPA chooses to arbitrarily ignore certain uses and related exposures.

ii) *TSCA's overall structure requires EPA to consider all of the conditions of use.*

TSCA provisions direct EPA to prepare risk evaluations and the related findings for "chemical substances," *as a whole*, not for specific or limited conditions of use of those substances. For example, the risk management provision expressly requires EPA to address risks when the risks arise from combined exposure. TSCA § 6(a) provides that: "If [EPA] determines in accordance with [the risk evaluation provision] that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, *or that any combination of such activities*, presents an unreasonable risk of injury to health or the environment," then EPA must issue a risk management rule. 15 U.S.C. § 2605(a); *see also* 15 U.S.C. § 2608(a) (using same language in provision governing requests to other federal agencies to address risks). Thus, if "any combination" of conditions of use presents an unreasonable risk, EPA must issue a risk management rule. But EPA must analyze *all* of these activities to assess whether *any combination* presents a risk.

When describing the end of a risk evaluation, TSCA requires EPA to make a finding about the "chemical substance" with no reference to conditions of use. *See, e.g.*, 15 U.S.C. § 2605(c)(1), (*i*) ("If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A)," then EPA must issue a regulation to address the unreasonable risk.). The absence of any reference to conditions of use makes it clear that EPA must make a finding for a chemical substance as a whole, not one limited to certain conditions of use. Notably, in the final prioritization rule, EPA correctly reasoned that this type of language indicated that EPA had to consider *all* uses in prioritization. *See* 82 Fed. Reg. 33,753, 33,755 (July 20, 2017) ("The statute directs EPA to make prioritization determinations on a 'chemical substance' or 'substance,' not on 'uses,' *see, e.g.*, 15 U.S.C. §§ 2605(b)(1)(A)-(C), and in most cases, without reference to 'the conditions of use.'"). This reasoning equally applies to risk evaluations.

iii) *TSCA's purpose, as well as basic logical reasoning and the best available science, require EPA to consider all conditions of use to assess a chemical substance as a whole.*

The purpose of the risk evaluation is to analyze the risks of a substance based on an assessment of its hazards and exposures. Ignoring potential exposures at the outset undermines that purpose. And science and logic do not support EPA's exceptions. For example, EPA states that it may disregard so-called "de minimis" exposures from conditions of use that occur in a closed system or use as an intermediate (p.12). But intermediates are often not completely consumed in chemical reactions and may remain as a residual in final reaction products. *See, e.g.*, California Department of Toxic Substances Control, Spray Polyurethane Foam Systems Containing Unreacted Methylene Diphenyl Diisocyanates, http://www.dtsc.ca.gov/SCP/Spray_Polyurethane_Foam.cfm (last visited Sept. 18, 2017). So the presumption that intermediates lead to a "de minimis" exposure is often contrary to the scientific evidence. In addition, intermediates must still be manufactured as well as typically being stored, transferred, or distributed, all of which are activities that can lead to exposures – including to workers, whom TSCA expressly identifies as a "potential exposed or susceptible subpopulation." Similarly, unintended impurities or contaminants can nonetheless lead to exposures and hence risks to human health or the environment, the significance of which needs to be determined in conducting a risk evaluation. *See infra* at pp.10-11 (discussing 1,4-dioxane). Ignoring them at the outset is contrary to the purpose of TSCA and risk evaluations, as well as the law's requirement that EPA rely on the best available science.

To be sure, EDF generally agrees with EPA's statement that "all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk." 82 Fed. Reg. at 33,734. Legally, EPA may be able to provide a concise and scientifically valid finding that a particular condition of use—such as the use phase of a chemical used as an intermediate—leads to little or no exposure and risk in a particular case, based on less than an in-depth analysis. And TSCA does not require a quantitative evaluation when a qualitative evaluation is determined and documented to be appropriate. But TSCA does not authorize EPA to simply "exclude" conditions of use at the outset as a matter of legal discretion. Furthermore, EPA must provide a scientific, data-backed rationale for why it decides a less extensive evaluation is sufficient, and cannot merely rely on a lack of data for such a decision.

EPA is imposing blinders on its analysis by asserting its authority to refuse to look at certain conditions of use, including known uses and disposals, and the result is that EPA is overlooking exposures in the real world. This approach is both contrary to law and arbitrary and capricious, as explained *infra* at Part I.D.

iv) *The legislative history does not justify or even lend support to EPA's approach.*

To justify its new position, EPA has emphasized the "legislative history" (p.11). But the legislative history, read as a whole, does not support EPA's approach. In the risk evaluation rule, EPA claims that the "legislative history of the amended TSCA *** explicitly states that the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation." 40 Fed. Reg. at 33,728 (citing 114 Cong. Rec. S3519-20 (daily ed. June 7, 2016) (statement of Sen. Vitter)). EPA relies on a floor

statement from a single Senator, which is one of the least illuminating forms of legislative history. EPA ignores that the rest of the legislative history reveals that other Senators thought that the statutory language would require EPA to consider all conditions of use in risk evaluations under the Lautenberg Act. Four principal Democratic negotiators of the legislation submitted a statement to the record that: "[t]he definition of 'conditions of use' described above plainly covers all uses of a chemical substance." 114 Cong. Rec. S3516 (daily ed. June 7, 2016). Similarly, when explaining why the bill expressly "grandfathered" in prior risk assessments (such as for Methylene Chloride), these negotiators explained that the provision was necessary because those "risk assessments for these chemicals were not conducted across all conditions of use." *Id.* at S3519. This explanation clearly reflects that *future* risk evaluations under TSCA would have to be conducted "across all conditions of use."

Unlike the text and structure of TSCA, the legislative history is somewhat ambiguous at points, although, if anything, it supports the position that EPA must consider "all conditions of use" since more Senators expressed that view and they did so in a formal statement.

B. Conditions of use expressly include certain so-called legacy uses and associated disposals.

In each of the scopes EPA stated that it *will* exclude so-called "legacy uses" and "associated disposal," (p.12) and EPA appears to rely on its reasoning from the risk evaluation rule. 82 Fed. Reg. at 33,729-30. EPA has asserted that no statutory text addresses this issue, and EPA stated that the use of the phrase "to be" in the definition of "conditions of use" implies a prospective application. 82 Fed. Reg. at 33,730; *see* 15 U.S.C. § 2602(4) (defining conditions of use to "mean[] the circumstances *** under which a chemical substance is intended, known, or reasonably foreseen *to be* manufactured, processed, distributed in commerce, used, or disposed of") (emphasis added). EPA also (inaccurately) asserted that it did "not have an effective tool to address risks found to arise from uses in consumer settings if there" is no on-going manufacture, processing, or distribution. 82 Fed. Reg. at 33,730. But none of this reasoning survives scrutiny.

EPA's argument based on tense clearly does not apply to the legacy uses and associated disposals. If a chemical substance is present in a product or material that an industrial, commercial, or residential consumer is still using, then the substance is known "to be" used in that circumstance. Similarly, if a substance has not been disposed of yet, its disposal is in the future and reasonably foreseeable. As a result, these "legacy uses" and "associated disposal[s]" fall squarely within TSCA's definition of "conditions of use," which includes the "circumstances *** under which a chemical substance is *** known *** to be *** used, or disposed of." 15 U.S.C. § 2602(4). EPA has presented no textual basis for treating the first three participles in the list in this definition (manufactured, processed, and distributed in commerce) differently than the last two participles (used and disposed of).

EPA's theory that § 6 focuses on the "continuing flow of chemical substances" in "their lifecycles" (p.12) completely ignores that the use and disposal of a chemical is *part* of the lifecycle of a chemical, as defined by Congress in TSCA. Indeed, chemicals that are still in use are still "distributed in commerce" as that term is defined in TSCA. 15 U.S.C. § 2602(5). In the final risk evaluation rule, EPA stated that it

"believes the statute is better interpreted to focus on the prospective flow of the chemical substance," 80 Fed. Reg. at 33,730, but Congress expressly covered substances *after* their introduction into commerce as well.

EPA also justified its decision to ignore legacy uses by claiming it lacks tools to address risks from uses in consumer settings if there is no on-going commercial manufacture, processing, or distribution. 80 Fed. Reg. at 33,730. But TSCA § 6(a) expressly provides EPA with authorities that could manage some of these risks, even if it does not provide as broad authority as it does over manufacturers and processors. *See* 15 U.S.C. § 2605(a). For example, at risk management, EPA may impose "[a] requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture." *Id.* § 2605(a)(5). For example, EPA could ban the sale or future use of products containing a chemical even if that chemical is no longer in production in the United States, or EPA could require that such items be labeled. EPA may also impose "[a] requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or *by any other person* who uses, or disposes of, it for commercial purposes." *Id.* § 2605(a)(6)(A) (emphasis added).

In any event, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Indeed, in order to assess real-world risks of a chemical using the best available science, EPA needs to consider even those exposures over which it has limited or shared control. This approach is particularly appropriate given TSCA § 9's referral provisions.

C. The text and overall structure of TSCA makes it clear that EPA has to analyze uses, even if they have been assessed by another agency or are within another agency's jurisdiction.

EPA also stated that it may "exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risk" (p.12). But EPA provides no textual basis for ignoring those uses, which are often "circumstances *** under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Nothing in the risk evaluation provision or definition of conditions of use authorizes EPA to ignore conditions of use because of other agencies' jurisdiction over chemical substances. And several other provisions of TSCA indicate that Congress intended for EPA to consider such exposures, except to the extent Congress explicitly provided otherwise.

First, TSCA § 9(a) provides a detailed procedural mechanism for EPA under certain circumstances to request for another federal agency to address an unreasonable risk arising from a chemical substance that EPA has identified. 15 U.S.C. § 2608(a). This request then triggers a number of duties for both EPA and the other agency, requiring one of the two agencies to take action to address the risk. Thus Congress intended for EPA to prepare risk evaluations analyzing uses that might be addressed by another agency, and Congress created a substantive and procedural mechanism to resolve overlapping jurisdiction only *after* completing the risk evaluation. If EPA could just ignore risks arising from

conditions of use that fall within other agencies' jurisdiction, or if Congress meant for EPA to defer to those agencies' current regulatory approach to those chemicals at the outset before conducting a risk evaluation, then EPA might never make the finding that triggers the § 9(a) process. Here again, Congress expressly chose to separate risk evaluation and risk management into different procedural steps, to ensure that EPA provided a robust risk evaluation uncolored by risk management concerns. Given that Congress expressly addressed the issue of overlapping regulatory jurisdictions in TSCA § 9, EPA cannot avoid those procedures by simply ignoring uses that fall within another agency's jurisdiction. Furthermore, EPA is expressly required to evaluate exposures from combinations of activities, which it cannot do if it excludes conditions of use at the outset that have been evaluated or regulated by another agency, particularly when that risk management is not an outright ban.

Second, Congress expressly exempted certain regulated chemicals or uses of chemicals from EPA's authority when it defined "chemical substance" in TSCA § 3(2). 15 U.S.C. § 2602(2)(B). For example, "chemical substance" does not include certain materials as defined in the Atomic Energy Act of 1954. *See id.* § 2602(2)(B)(ii), (iv). Thus, when Congress intended for EPA not to regulate certain conditions of use because they were regulated under other specific federal statutes, Congress expressly excluded those conditions of use. That Congress chose a limited, specific set of exclusions indicates that Congress did not intend for EPA generally to ignore other conditions of use even where they fall under other federal regulatory schemes.

D. The scopes contain incoherent and arbitrary and capricious reasoning because of EPA's approach to conditions of use.

EPA's illegal approach to "conditions of use" leads it to put "blinders" on regarding certain uses, exposures, and risks. The result is "arbitrary, capricious, [or] an abuse of discretion" under the APA, 5 U.S.C. § 706(2)(A), because it will lead EPA to have considered "factors which Congress has not intended it to consider [and] entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. It also violates several provisions of TSCA § 26 because by ignoring uses, exposures, and related information, EPA will not be acting "consistent with the best available science," EPA will not base decisions on "on the weight of the scientific evidence," and EPA will not "take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(h), (*i*), (k). In addition, because EPA's distinction is a false one untethered to the information, EPA seems to treat certain conditions of use inconsistently throughout the documents.

For example, in the 1,4-dioxane scope, EPA states that it will not consider risks arising from 1,4-dioxane when it is present as a by-product or residual contaminant from the manufacture of other chemicals. *See* 1,4-Dioxane, Scope at p.21, Docket ID: EPA-HQ-OPPT-2016-0723. But EPA identifies numerous products that "potentially contain[] 1,4-dioxane as a residual contaminant, including paints, coatings, lacquers, ethylene glycol-based antifreeze coolants, spray polyurethane foam, household detergents, cosmetics/toiletries, textile dyes, pharmaceuticals, foods, agricultural and veterinary products," as well as "magnetic tape and adhesives." *Id.* These are known and reasonably foreseen conditions of use

leading to exposures to 1,4-dioxane, and EPA's decision to ignore them when analyzing whether this chemical presents an unreasonable risk is arbitrary and capricious. EPA's theory is that it cannot regulate these impurities until it analyzes ethoxylated chemicals (*id.* at 8), but EPA provides no reasoned legal theory for why it could not act to regulate these exposures after this risk evaluation. *Id.* Even more problematically, EPA staked out the position that "EPA may choose not to include a particular impurity within the scope of any risk evaluation." 82 Fed. Reg. at 33,730. So these exposures may never be analyzed.

In addition, EPA acknowledges that 1,4-dioxane is often used as an intermediate or a reactant and that "the 1,4-dioxane would react either fully *or to a lesser extent*. Following completion of the reaction, the produced substance *may or may not be purified further*, thus removing unreacted 1,4-dioxane (if any exists). Reacted 1,4-dioxane is *assumed* to be destroyed and is thus not expected to be released or cause potential worker exposures." *See* 1,4-Dioxane, Scope at p.56, Docket ID: EPA-HQ-OPPT-2016-0723 (emphases added). But EPA never acknowledges that the unreacted 1,4-dioxane could lead to exposure. And that document provides no explanation, documentation, or quantification supporting the underlying assumption that 1,4-dioxane is destroyed or reacted. Indeed, from the description, it seems clear that it often will not be destroyed. The assumption in the last quoted sentence is contrary to the statements made in the proceeding sentences.

EPA's scopes should indicate that it will assess the reasonably available information on hazards and exposures for the substances (see Section II below), and that information should inform EPA's evaluation of the risks associated with "the conditions of use." If there is a real-world exposure, then EPA should not ignore it.

II. EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA §§ 4 and 8 to obtain additional information.

TSCA orders EPA to consider "available" and "reasonably available" information in crafting a risk evaluation, 15 U.S.C. §§ 2605(b)(4)(F)(i), 2625(k), and under the new risk evaluation rule, EPA defined "[r]easonably available information" to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation." 40 C.F.R. § 702.33, promulgated at 82 Fed. Reg. 33,748 (July 20, 2017). Thus, under its own rule, EPA has to consider information that it "can reasonably generate, obtain, and synthesize."

Yet, the scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is *reasonably* available information.

A. Any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities.

EPA must promulgate reasonable regulations under § 8(d) and 8(a) to obtain information about hazards, exposures, and conditions of use for these ten chemicals; EPA should also exercise its authority under § 8(c) to obtain additional information. Consistent with TSCA § 8(a)(5), EPA can take steps to reduce unnecessary and duplicative reporting. Because TSCA requires EPA to produce robust risk evaluations that reflect "reasonably available" information, and information available under these authorities is "reasonably available" on its face, EPA must use these authorities to fulfill its duty. Moreover, these first ten risk evaluations are crucial to establishing the credibility of the TSCA program under the Lautenberg Act, and EPA can only establish that credibility by using its full authority to obtain "reasonably available information" on chemicals, as required by the law. Collecting this information is also necessary to fulfill EPA's duty to use the best available science under TSCA § 26.

TSCA § 8(d) allows EPA to "require any person who manufactures, processes, or distributes in commerce *** any chemical substance or mixture *** to submit to the Administrator—lists of health and safety studies: (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person; or (C) reasonably ascertainable by such person." 15 U.S.C. § 2607(d). EPA should issue § 8(d) rules for these ten chemicals. To obtain a complete picture, EPA should expressly require both manufacturers and processors to report on these chemicals under the § 8(d) rules. *See* 40 C.F.R. § 716.5(c).

EPA has previously issued such rules for some of these chemicals, but two decades have passed since the last of those rules sunsetted, so new, additional health and safety studies are almost certainly available. For example, the methylene chloride and asbestos reporting periods sunsetted in 1992, the HBCD reporting period sunsetted in 1995, and the perchloroethylene reporting period sunsetted in 1997. *See* 40 C.F.R. § 716.120. Given scientific advancement over the last two decades, issuing new rules calling in health and safety studies would likely provide EPA with additional valuable information to assess the hazards, exposures, and risks posed by these chemicals. It appears that EPA has never issued such rules for Carbon Tetrachloride, Trichloroethylene, Pigment Violet 29, 1-Bromopane, 1-4 Dioxane, and N-Methylpyrrolidone. *See* 40 C.F.R. § 716.120. Thus, issuing § 8(d) rules for those chemicals is even more important.

Notably, EPA's regulations correctly interpret "health and safety study" broadly to incorporate "[a]ny data that bear on the effects of a chemical substance on health or the environment." 40 C.F.R. § 716.3. These include numerous tests for health and environmental effects. *See id.* They also include monitoring data and other assessments of human and environmental exposures. *See id.* EPA should also review these studies upon receipt and request underlying data under 40 C.F.R. §§ 716.10(a)(4), 716.40(a). EPA should also separately request reporting on these chemicals when they are manufactured, processed, or distributed as an impurity, 40 C.F.R. § 716.20(a)(9), because impurities may be an important source of exposure and thus risk, as explained above.

Under TSCA § 8(a), EPA may require manufacturers and processors to provide extensive information. *See* 15 U.S.C. § 2607(a)(2). EPA "shall, to the extent feasible" "not require reporting which is unnecessary or duplicative" and also "apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this title." *Id.* § 2607(a)(5). To avoid duplication, EPA need not request reporting on information EPA has already obtained through other recent submissions such as through the Chemical Data Reporting (CDR) process. *See* 40 C.F.R. Part 711. But the CDR process does not require manufacturers and processors to provide all information that EPA can reasonably obtain under TSCA § 8(a) which is relevant to the risk evaluations. For example, EPA should require reporting of: "[a]ll existing information concerning the environmental and health effects of" each chemical; "the byproducts resulting from the manufacture, processing, use, or disposal of each" chemical; more detailed information about exposures to these chemicals, including the duration, frequency, and timing of exposures; and additional information about disposal. *See* 15 U.S.C. § 2607(a)(2). In particular, EPA can require submission of any data available on releases or exposures in the workplace and environment, and those data would be crucially important to an accurate risk evaluation. To decrease the burden on industry, EPA should pursue both rulemakings simultaneously, and EPA can provide that when information is submitted under one rule, the same information need not be submitted under the other. But EPA should use both authorities to ensure that it does not miss any information that may fall within one authority but not the other.

In addition, EPA should rely on its request authority under TSCA § 8(c). Under TSCA § 8(c), "[a]ny person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture." 15 U.S.C. § 2607(c). EPA promulgated rules governing this recordkeeping requirement at 40 C.F.R. Part 717. The rules apply to most manufacturers and many processors. 40 C.F.R. § 717.5. Manufacturers and processors must maintain records of many types of allegations, as detailed in 40 C.F.R. §§ 717.5 and 717.10. The regulation defines "significant adverse reactions" to include, but not be limited to, many specific types of harm that are highly relevant to the ultimate question presented in a risk evaluation: "whether a chemical substance presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(b)(4)(A). Firms must maintain these records for 30 or 5 years, depending on the circumstances. 40 C.F.R. § 717.15(d).

EPA should use its authority to request these records on alleged significant adverse reactions caused by the ten chemicals analyzed in the scope documents and add them to the administrative record for the relevant chemical. EPA can request records from manufacturers and processors that reported the chemicals in response to any § 8(a) and 8(d) rules or in response to CDR reporting. *Id.* § 717.17. EPA can request those records by letter. *Id.* § 717.17(b). Finally, EPA can also notify all people holding such records to provide them by a notice in the Federal Register. *Id.* These records may provide valuable information on hazards, exposures, and conditions of use, since the records may reveal not only significant adverse reactions but also information about the specific exposure and use that may have caused the reaction.

B. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps.

EPA should make robust use of its § 4 authority to fill any gaps in information. EDF recognizes that time constraints apply to these first ten chemicals and thus some types of testing may not be possible, but going forward, EPA needs to use its authority fully and do so in a timeframe that ensures it will have all of the information it needs to conduct risk evaluations.

As EPA moves forward on the first 10 risk evaluations, it should first clearly identify *all* significant information gaps on hazards or exposures. Based on its own regulation, EPA must then use its authority under TSCA § 4(a)(2) to require the development of new information to fill those gaps wherever possible. Information that EPA can generate under TSCA § 4(a)(2) is reasonably available under EPA's own regulation as "information that EPA *** can reasonably generate [and] obtain *** for use in risk evaluations." 40 C.F.R. § 702.33. Thus, EPA should identify such information gaps and then promptly require the conduct of all testing that can be done and still meet the statutory deadlines for the risk evaluations.

TSCA § 4(a)(2) provides that EPA "may, by rule, order, or consent agreement require the development of new information relating to a chemical substance *** if the Administrator determines that the information is necessary *** to perform a risk evaluation under section 6(b)." 15 U.S.C. § 2603(a)(2)(A)(i). Congress provided this additional testing authority allowing EPA to require testing or other data development efforts solely upon a determination "that the information is necessary *** to perform a risk evaluation under section 6(b)." *Id.* In light of deadlines, EPA can and should use its order authority and does not need to make the additional findings required for a rule under TSCA § 4(a)(1).

In places in these scopes, EPA seems to be going out of its way to avoid using its information authorities. For example, in numerous places in these scopes, with respect to exposure, EPA indicates that "[f]or conditions of use where data are limited or not available, [it will] review existing exposure models that may be applicable in estimating exposure levels" (p.43). This language suggests that EPA will simply default to models rather than use its authority to get needed information. In EDF's view, EPA should first use its authorities under TSCA §§ 8 and 4 to fill those information gaps, rather than rely on models to compensate for lack of information. This is not to say that exposure models do not have a role, but they are not a basis for avoiding the obligation to collect information.

Our review of the scopes indicates that there are significant gaps in the information. Where possible EPA needs to fill those gaps. When it is not possible, consistent with TSCA § 26, EPA needs to identify those gaps and characterize the uncertainty in the draft risk evaluations. To cite just one example, in the scope for Methylene Chloride EPA completely fails to mention an information gap earlier identified in the Work Plan. Specifically, the 2014 Work Plan Assessment for Methylene Chloride identified both developmental neurotoxicity and immunotoxicity from chronic exposure as important data gaps, impacting the selection of the point of departure:

> There is uncertainty about chronic exposure impacts on the nervous system function. The nervous system has been well studied and identified as very sensitive for acute effects. However, there is a paucity of data on chronic neurological impacts, especially developmental neurotoxicity. Likewise, there is limited information about immunotoxicity following chronic exposure to DCM. Existing hazard studies are not sufficient for dose response analysis to provide a lower point of departure than existing adverse findings in the liver from chronic exposures."

See Methylene Chloride: Paint Stripping Use, TSCA Work Plan Chemical Risk Assessment at p.115, https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf

C. If EPA already has relevant information, it is reasonably available and EPA should consider it.

The strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." *See, e.g.*, Asbestos literature at p.13. But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation *** is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available, EPA must review it.

In addition, much of this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. First, historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act. Second, the Lautenberg Act greatly increased the requirements companies must meet to assert CBI claims. For example, information only qualifies for protection if the submitter asserts *and* substantiates that it has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c). Thus, even if the information once merited protection, it may no longer be confidential under the standards of TSCA § 14. Third, as a general rule, TSCA § 14(b)(2) provides that health and safety studies and information from health and safety studies are not entitled to confidential treatment, so much of this information may not be confidential under that provision.

To fulfill its duties under TSCA, EPA must review this reasonably available information and identify that which is potentially relevant to the risk evaluations. Where information is relevant, EPA should also consider whether the information meets the strict requirements for nondisclosure under TSCA § 14. If not, EPA should add it to the administrative record for review by the public. Whether or not it meets those requirements, EPA should then determine whether and how to consider the information in evaluating these chemicals. Notably, TSCA § 26(j) requires that, "subject to section 14," EPA "shall make

available to the public *** a list of the studies considered by [EPA] in carrying out each such risk evaluation, along with the results of those studies." 15 U.S.C. § 2625(j).

D. When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information.

In the literature searches, EPA sometimes states that it relied on recent assessments, and then only performed research for dates beyond those assessments. *See, e.g.*, 1,4-Dioxane, Strategy for Conducting Literature Searches for 1,4-Dioxane: Supp. File for the TSCA Scope at p.7, 9-10, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0047. EPA needs to provide a short analysis presenting its review of the prior analysis to ensure it adequately captured and addressed all reasonably available information as of the date of its publication, particularly given the expanded obligations under the Lautenberg Act. If EPA finds it was not adequate, then EPA should broaden its literature search.

III. EPA needs to take additional steps to ensure both the completeness and accuracy of the information it relies upon.

As explained above, EPA should rely on its authorities under TSCA §§ 8 and 4 to obtain all reasonably available information. Those authorities include a number of measures to ensure the accuracy and completeness of the data relied upon. To the extent EPA relies on voluntarily submitted information, EPA needs to take additional steps to ensure the accuracy and completeness of the information. Otherwise, EPA will violate TSCA § 26 by failing to make decisions "in a manner consistent with the best available science." 15 U.S.C. § 2625(h)

A. EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals.

EPA has requested in each of the scopes that industry and other stakeholders provide information. While this voluntary request was a reasonable first step towards obtaining the necessary information, EPA has failed to provide any account for how this voluntary approach to collecting information will result in EPA obtaining all "reasonably available" information as EPA has defined that term. There are several obvious problems and limitations with this voluntary approach which EPA has not even acknowledged, much less addressed.

First, a voluntary call is much less likely to produce all of the necessary information than rules mandating that affected parties provide the requested information. If manufacturers and processors are legally required to provide the information, that legal obligation provides a strong incentive for them to collect and submit all relevant information. Absent that incentive, some companies may choose to focus time and attention on other matters. Indeed, the burdens (whether one considers them heavy or light) of collecting and submitting information counsel in favor of issuing mandatory rules. *If* the process of

collecting and submitting the information is not onerous or difficult, then using rules to require the submission of the information will do little if any harm to the regulated industry, and use of rules will ensure EPA has a complete picture and increase credibility. Alternatively, to the extent that the process is onerous or difficult, it is even more important that EPA *require* the submission of the information, because otherwise those burdens will likely discourage stakeholders with relevant information from collecting and submitting the information.

Second, EPA has provided no empirical evidence establishing that this voluntary approach will result in EPA obtaining all "reasonably available" information. Unless EPA has some empirical basis for stating that the voluntary approach will allow EPA to obtain all reasonably available information that it can obtain under its legal authorities, EPA must rely on its existing authorities to obtain a complete set of information.

Indeed, EPA's prior experience with voluntary reporting provides strong evidence that a voluntary approach is unlikely to provide complete and accurate data. For example, an EPA advisory committee called for the development of nanomaterial reporting rules in 2005, but EPA instead spent several years developing and carrying out a voluntary reporting program, the Nanoscale Materials Stewardship Program (NMSP). This voluntary reporting program produced minimal information as revealed by EPA's 2009 interim report on the NMSP. Nanoscale Materials Stewardship Program, Interim Report, OPPT (Jan. 2009), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0572-0003. "[I]n the report EPA estimated that companies provided information on only about 10 percent of the chemical substances manufactured at the nanoscale that may be commercially available in 2009." 80 Fed. Reg. 18,330, 18,334 (April 6, 2015). In 2017, over a decade after the data need was identified, EPA finally finalized a § 8(a) reporting rule to acquire the data. 82 Fed. Reg. 3641 (Jan. 12, 2017). Given the past failures of voluntary approaches, EPA should not rely on them here.

Third, manufacturers and processors of these chemicals have a vested interest in EPA finding that the chemicals do not present an unreasonable risk. A no-unreasonable-risk finding reduces the likelihood of government regulation, including potential restrictions on risky chemicals, and it may reduce any stigma they may otherwise face in the marketplace. The financial costs of regulation may ultimately be very high for some specific firms and individuals, and even if not, many firms and individuals may *believe* that the costs of regulation will be high. These companies have a "financial interest" in the outcome of these proceedings, and they are not impartial. *See, e.g.*, 28 U.S.C. § 455(b)(4) (requiring Judges to disqualify themselves in proceedings where they have a financial interest). Because of this reality and appearance of partiality, relying solely on voluntary measures decreases the credibility of these risk evaluations.

Relying solely on voluntary presentation of information raises the concern that the companies or trade associations may present an incomplete or skewed picture. Companies and trade associations may choose to "cherry pick" information and provide only the information that paints their chemicals in favorable light. They may provide only summaries of information that reflect conscious and subconscious judgment calls that result in unduly favorable conclusions; and without access to the full information neither EPA nor the public can independently assess such conclusions. They may choose

not to review records robustly when the review may disclose unfavorable information. They may seek to put their best foot forward and describe the ideal scenario of use and safety measures. Or, if they have unfavorable information, they may choose not to provide any information at all and simply not participate in these proceedings.

To be sure, members of the regulated community are crucial sources of information about their chemicals' uses, hazards, and exposures, but EPA cannot simply assume that they will voluntarily disclose unfavorable or complete information about their practices and products. *See* THE FEDERALIST NO. 51 (James Madison) ("If men were angels, no government would be necessary. *** [E]xperience has taught mankind the necessity of auxiliary precautions."); *Williams v. Pennsylvania*, 136 S. Ct. 1899, 1905-06 (2016) ("Bias is easy to attribute to others and difficult to discern in oneself. *** This objective risk of bias is reflected in the due process maxim that 'no man can be a judge in his own case and no man is permitted to try cases where he has an interest in the outcome.'"). Here, manufacturers and processors obviously have an interest in the outcome, and EPA must craft its procedures and approaches with that reality in mind. Requiring the submission of information is the safest approach to ensuring that these parties provide all relevant information, and that is in turn crucial to establishing and demonstrating the credibility of this process.

If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information. First, EPA can require that certain information and underlying information be provided in full, which ensures completeness. In addition, a § 8(d) rule requires that people engage in an adequate search of records. 40 C.F.R. § 716.25. Second, submitters must file certification statements by authorized officials that certify that the submitted information has been submitted in compliance with the requirements of this process. *See, e.g.*, 40 C.F.R. § 711.15(b)(1). Third, submitters often must retain records of required submissions for a period of five years, and the retention of records can help encourage accurate reporting since those records would be available should a submission latter be investigated. *See, e.g.*, 40 C.F.R. § 711.25. None of these features apply to the voluntary requests for information EPA has indicated it is relying on.

In addition, as EDF has explained in prior comments, there are numerous reasons that it is important that the public have access to full studies and the underlying information, not simply robust or other study summaries. *See, e.g.*, EDF Comments on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act, Comment at p.37, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074. Without access to full studies, the public will be challenged or unable to assess and comment on the quality of the studies used by the agency. *Id.* EDF reincorporates and reiterates the numerous points made in support of public access to the full studies here. *Id.* These points also support the importance of EPA obtaining the full studies.

B. For voluntary submissions, EPA should take additional steps to ensure completeness and accuracy and to vet information based on underlying data.

To the extent it relies on voluntary submissions, EPA can and should take additional steps to better ensure that the voluntary information it receives is accurate and complete. EPA would need to develop a far more rigorous and structured process than it currently has. For example, EPA's submission process does not appear to require anyone to certify that the information in their comments is accurate or complete to the best of their knowledge. EPA should consider approaches for vetting statements and assertions, particularly when made by entities with a financial interest in the outcome of these risk evaluations.

EPA should also request that submitters always provide full studies, as well as underlying data whenever reasonably available or obtainable. Setting aside concerns about partiality, EPA needs the underlying data to ascertain the accuracy of the information and associated statements or conclusions, as well as to determine how much confidence or uncertainty applies to a particular submission.

In addition, EPA should seek input directly from workers for manufacturers and processors, providing them an easy method to submit information on workplace practices and conditions independently from management. EPA needs to take steps to allow workers to provide input in a manner that reduces the risks of any potential retaliation from management.

To give a few specific examples from the scopes:

In the Perchloroethylene scope (also known as tetrachloroethylene or PCE), EPA cites the Vinyl Institute's comments for the fact it can be a residual or byproduct in the manufacture of other chemicals. *See* Perchloroethylene, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0732 (citing comment at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0013). That comment, in turn, contains a table claiming to summarize the approximate concentrations of Perchloroethylene in light and heavy end liquid intermediate streams yielded in the EDC/VCM process for manufacturing each of four chlorinated organic substances. The comment states that there is no residual Perchloroethylene in light liquid ends and 1.1% by typical weight in heavy liquid ends. But the comment does not provide or cite any underlying data supporting these findings. When commenters provide summary statements along these lines, EPA should give them little weight unless it also receives the underlying data to ensure that the reported results or conclusions drawn accurately reflect real-world conditions and to assess the level of certainty and scope of applicability that EPA can attribute to the results or conclusions. This point holds for all of the percentages set forth in that table, including those for the other three products.

Similar concerns arise for many of the other scopes. For example, in the Carbon Tetrachloride scope, EPA states that: "there are public comments, EPA-HQ-OPPT-2016-0733-0005 [3M] and EPA-HQ-OPPT-2016-0733-0017 [ACC], stating that carbon tetrachloride may be present in a limited number of industrial products with chlorinated ingredients at a concentration of less than 0.003% by weight." Carbon Tetrachloride, Scope at p.20, Docket ID: EPA-HQ-OPPT-2016-0733. But upon examining those

comments, they do not provide any of the underlying data or enough information to assess accuracy of the statement or the level of uncertainty that should apply to the results. The ACC comment is particularly difficult to assess. It involves multiple levels of hearsay, with ACC reporting statements that companies reported to it. Some of those companies acknowledge they are also relying on hearsay from suppliers and have not taken steps to confirm these concentrations. Those suppliers might also be relying on hearsay; it is simply not clear what the bases are for some of these values. Hearsay is, of course, particularly problematic when the statement serves the interest of the person submitting the evidence. *See, e.g.*, FED. R. EVID. P. 804(b)(5) (exception for statements against interest). As such, these concentrations arguably provide at best a "lower bound" estimate; they are not sufficient in terms of establishing that the actual concentrations are not higher. While no formal hearsay rule applies to these administrative proceedings and the hearsay evidentiary rule generally has limited applicability to technical studies and business records, it is relevant to the weight EPA should give these reported values given these circumstances. ACC does not disclose the companies providing the information, making it impossible for EPA to independently address these kinds of concerns. In addition, ACC's comment often fails to provide any clarity or detail as to how the concentrations were measured or assessed, much less provide the data underlying these claimed concentrations. The ACC comment asserts concentrations for 1,4-Dioxane, Pigment Violet 29, N-Methylpyrrolidone (NMP), Methylene Chloride (DCM), Carbon Tetrachloride, and HBCD, but for most of these concentrations, it is impossible for EPA or the public to assess whether they are accurate. For some of these concentrations, the comment states that Safety Data Sheets and Technical Data Sheets are provided with the comments, but EDF did not find any attachments with the comment containing those materials. In sum, EPA needs to scrutinize these voluntary submissions carefully and ensure access to the underlying information, which is necessary to assess the accuracy of the statements therein.

In the asbestos scoping document, EPA acknowledged that the analysis of the Chlor-Alkali industry was "primarily based on information provided by either the chlor-alkali industry or [the American Chemistry Council] and is meant to represent typical practices." *See* Asbestos, Scope at p.54, Docket ID: EPA-HQ-OPPT-2016-0736. EPA correctly recognized that EPA should "further evaluate how representative the processes witnessed at these two facilities are of processes at other plants." *Id.* at 23. EPA should take measures to ensure that its process will in fact accurately assess the full range of existing practices, relying on independent data where possible. Where independent data are unavailable, EPA should reach out to workers directly to better determine actual practices. Even when companies have good practices on paper, those practices may not be the reality on the ground.

EPA also needs to carefully scrutinize statements to ensure it correctly interprets them.

IV. These scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations.

Broadly viewed, the scopes do not meet several of the statutory requirements of TSCA. TSCA § 6(b)(4)(D) requires that EPA "shall, not later than 6 months after the initiation of a risk evaluation,

publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D). These scopes do not fully satisfy these requirements. Some aspects are plainly illegal under *any* interpretation of the statute, for the reasons given above, such as the statement that "EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11).[1] But many other aspects, while problematic, can be resolved by EPA in the next step: its development of problem formulations.

It is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. EDF believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified. With respect to susceptible populations, EPA should consider workers and, in most cases, pregnant women and children, to be potentially exposed or susceptible subpopulations. We identify below a number of specific examples where EPA's scopes are unclear and merit further study.

A. 1,4-Dioxane

EPA states: "EPA evaluated the weight of the evidence for cancer in humans and animals and concluded that 1,4-dioxane is 'likely to be carcinogenic to humans' based on evidence of carcinogenicity in several 2-year bioassays." 1,4-Dioxane, Scope at p.24, Docket ID: EPA-HQ-OPPT-2016-0723. However, certain language in this section suggests that EPA may not include cancer as a hazard endpoint in the risk evaluation.

Indeed, EPA almost seems to suggest that inconclusive evidence regarding the "mode of action by which 1,4-dioxane produces liver, nasal, peritoneal (mesotheliomas) and mammary gland tumors" might form a basis for disregarding the evidence of such hazards. *Id.* at 35. As a general matter, EPA should not exclude observed hazards simply because the underlying MOA is not fully delineated or understood, doing so would significantly and inappropriately jeopardize the robustness and health-protections of the risk evaluation. If there is evidence of hazard, EPA should include it in the risk evaluation, even if the precise mode of action is not yet understood.

[1] As explained above, EPA puts too much weight on a floor statement from a single Senator, David Vitter. But even Senator Vitter stated that EPA must consider all conditions of use identified in the scope. *See* 114 Cong. Rec. S3520 (daily ed. June 7, 2016) (statement of Sen. Vitter). Despite that statement, the scoping documents all state that "during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation" (p.11). Thus, EPA is inconsistent in how much weight it gives to Senator Vitter's statements, and EPA's current interpretation appears to contradict the views expressed throughout the legislative history by every single legislator. If EPA excluded uses identified in the scope, such as uses in the chlor-alkali industry (e.g., pp.20, 23-24), then EPA will be acting contrary to Senator Vitter's statement.

B. Perchloroethylene

The scope for Perchloroethylene states that "EPA expects to consider hazards identified in the recent assessment by the EPA Integrated Risk Information System (IRIS) Program: neurotoxicity, kidney toxicity, liver toxicity, developmental and reproductive toxicity and cancer. Support for an association with immune and blood effects was less well characterized." Perchloroethylene, Scope at p.11, Docket ID: EPA-HQ-OPPT-2016-0732. It is unclear from the scope whether EPA intends to include immune and blood effects in particular.

C. Trichloroethylene (TCE)

In the scope for TCE, EPA suggests that TCE's use as a spot remover will not be analyzed because it was previously analyzed in a risk evaluation. TCE, Scope at p.25, Docket ID: EPA-HQ-OPPT-2016-0737. That approach may be reasonable if EPA finalizes its proposed ban on this use of TCE to address those risks, as discussed more below. But that approach only applies to those spot remover uses that have previously been analyzed, specifically commercial dry cleaning facilities. This risk evaluation needs to consider TCE's use as a consumer spot remover. Those uses have not been analyzed in-depth, and the 2014 work plan assessment recognized that some such products may contain TCE as a main ingredient. *See* Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses, TSCA Work Plan Chemical Risk Assessment at p.52, https://www.epa.gov/sites/production/files/2014-11/documents/tce_opptworkplanchemra_final_062414.pdf.

D. N-Methylpyrrolidone (NMP)

The NMP scope has numerous inconsistencies with respect to its identification of the endpoints to be assessed. EPA begins by acknowledging that a "number of human health hazards have been identified for NMP including adverse effects on hepatic, renal, immune, reproductive/developmental and central nervous systems." N-Methylpyrrolidone, Scope at p.36, Docket ID: EPA-HQ-OPPT-2016-0743. EPA also states that: "EPA expects to consider all potential hazards associated with NMP." *Id.* EDF completely agrees with that approach. However, the description under section 2.42 Human Health Hazards indicates that EPA intends to focus on a narrower set of hazards (acute toxicity and reproductive/developmental toxicity), and provides no justification or even explanation for excluding some of the hazards that it previously identified.

E. Potentially exposed or susceptible subpopulations

EPA also does not identify pregnant women, women of childbearing age, or the developing fetus as potential exposed or susceptible subpopulations for either N-Methylpyrrolidone (NMP) [NMP, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0743] or TCE [TCE, Scope at pp.37-38, Docket ID: EPA-HQ-OPPT-2016-0737], despite the fact that EPA's previous risk assessments on these two chemicals identify women of childbearing age and the developing fetus as a primary susceptible population (in addition to workers). EPA's failure to identify these populations in the scopes is both contrary to law and an abuse of discretion. TSCA § 3(12) defines "potentially exposed or susceptible subpopulation" to include "a

group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance *** , such as infants, children [or] pregnant women." 15 US.C. § 2602(12). Here, EPA has previously found that "women of childbearing age" are at greater risk of adverse health effects from these chemicals. 82 Fed. Reg. 7432, 7434 (Jan. 19, 2017); 82 Fed. Reg. 7464, 7467 (Jan. 19, 2017).

Furthermore, TSCA requires that EPA identify "the potentially exposed or susceptible subpopulations the Administrator expects to consider" in the scopes. 15 US.C. § 2605(b)(4)(D). While EPA has considered those at greater risk due to *increased exposure* in the scopes to some extent, the agency appears to defer the process of identifying populations with *greater susceptibility* to the problem formulation or risk evaluation stage: "In developing the hazard assessment, EPA will also evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s)." *See, e.g.*, NMP, Scope at pp.36-37, Docket ID: EPA-HQ-OPPT-2016-0743; 1,4-Dioxane, Scope at p.35, Docket ID: EPA-HQ-OPPT-2016-0723.

V. EPA needs to analyze potential exposures from distribution, as well as from known and reasonably foreseeable accidental exposures.

The scoping documents generally acknowledge the need to analyze activities related to a chemical's distribution, but EPA will need to analyze these exposures more robustly than the scopes currently reflect. *See, e.g.*, 1,4-Dioxane, Scope at p.22, Docket ID: Docket ID: EPA-HQ-OPPT-2016-0723.

The scoping documents give little, if any, attention to potential releases and exposures resulting from accidental releases. EDF does not suggest that EPA needs to consider every possible scenario, but the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks. For example, as and after Hurricane Harvey passed through Houston, over 40 sites released toxic chemicals into the environment. *See, e.g.*, More Than 40 Sites Released Hazardous Pollutants Because of Hurricane Harvey, https://www.nytimes.com/interactive/2017/09/08/us/houston-hurricane-harvey-harzardous-chemicals.html?_r=0. Given the *known* accidental releases, the huge number of petrochemical plants and refineries in the Houston area, and the likelihood that flooding there may become more common in light of climate change, such events are clearly reasonably foreseen and hence EPA needs to give more consideration to the potential for accidental releases.

VI. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures.

Language used in the scopes suggests that EPA may inaccurately assume that people comply with all warning labels and always use personal protective equipment (PPE). EDF strongly urges EPA to consider real-world exposures reflecting the reality of the sometimes low-compliance with or non-existence of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by

either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). And absent empirical evidence establishing the extent to which people are using these measures, EPA should assume that they may not be. Indeed, EPA's need for accurate information about actual compliance is another reason to rely on its authorities under TSCA § 8 to mandate that manufacturers and processors provide that information. In addition, it bears noting that reliance on PPE as a primary measure to protect workers is counter to OSHA's Industrial Hygiene Hierarchy of Controls (HOC), a long-standing principle that prioritizes measures to eliminate or reduce the presence of a hazard in occupational settings (e.g., substitution/use of less toxic chemicals and institution of engineering controls) over measures that shift burdens onto the workers themselves, such as through reliance on PPE and warning labels. The HOC exemplifies the best available science for creating safe, healthful workplace environments.

As an example of a problematic reference to PPE in the scopes, in the asbestos scope, EPA stated that "[d]ermal exposure is unlikely due to glove use in the workplace." Asbestos, Scope at p.37, Docket ID: EPA-HQ-OPPT-2016-0736. But EPA cites no evidence supporting this assumption. While gloves may be used in many workplaces, EPA needs to provide evidence of the extent of such use. Among other things, EPA correctly noted earlier that "certain conditions of use, such as a mechanic changing asbestos-containing brakes, may also result in dermal exposure." *Id.* at 35. Is there any evidence that all or even most mechanics wear gloves when changing brakes? Indeed, EPA should identify mechanics as a relevant potentially exposed or susceptible subpopulation based on their exposure to brakes.

In comments EDF has submitted in these dockets, EDF previously commented on the serious limitations of labeling and PPE, as well as the importance of adherence to the hierarchy of controls to limit workplace exposures. *See, e.g.*, EDF comments at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0046, March 15, 2017; and at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0052, November 21, 2016. EDF reincorporates and reiterates the points made in those comments here.

VII. EPA's decision not to examine uses addressed by its planned § 6(a) rules governing certain uses of TCE, DCM, and NMP is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses.

For Trichloroethylene (TCE), Methylene Chloride (DCM), and N-Methylpyrrolidone (NMP), EPA states that conditions of use previously examined will not be re-evaluated. TCE, Scope at p.9, Docket ID: EPA-HQ-OPPT-2016-0737; DCM, Scope at p.29, Docket ID: EPA-HQ-OPPT-2016-0742 ("This includes uses assessed in the U.S. EPA (2014a) risk assessment and therefore those uses are out of scope for the risk evaluation."); NMP, Scope at pp.20, 28, Docket ID: EPA-HQ-OPPT-2016-0743 ("This includes uses assessed in the previous EPA risk assessment (U.S. EPA, 2015) and therefore those uses are out of scope for the risk evaluation."). EPA has previously found these uses even by themselves present unreasonable risks to human health. In addition, these uses have the potential to increase the total

exposure of people to these chemicals. As a result, EPA can only reasonably exclude these uses if it finalizes the proposed rules to ban these uses. EDF strongly supports those bans for the reasons it articulated in its prior comments.

If EPA does not finalize these bans, then excluding these uses is both contrary to law and arbitrary and capricious. By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is *** known *** to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses *unless* EPA has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals.

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EDF appreciates the opportunity to provide comments and EPA's consideration of them.